CP 200™ Spirometry Option

Directions for Use

Welch Allyn®

Advancing Frontline Care™

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About This Manual

This manual is written for clinical professionals performing pulmonary function testing. Users must be familiar with measurements and the clinical significance of basic spirometry products.

Before using the spirometer, all users and technicians must read and understand this manual and all other information accompanying the CP 200 spirometry option and the CP 200 electrocardiograph.

Caregivers need to know how to properly coach patients, to recognize acceptable waveforms, and to know whether results meet ATS reproducibility criteria.

The hospital's Biomedical/IT support staff shall require primary skills including disciplines related to maintenance and servicing computer controls/platforms.

It is recommended that users attend a certified spirometry training course. The instructions given here are only a guide and should not be used to train a technician.

For definitions of specialized terms and abbreviations used in this manual, see "Glossary" on page 77.

Note This manual supplements the CP 200 electrocardiograph manual, entitled *CP 200 12-Lead Resting Electrocardiograph Directions for Use*.

See the electrocardiograph manual for procedures that are common to both ECG and spirometry functions, such as how to move through the menus, how to search for patient data, or how to edit the medication list.

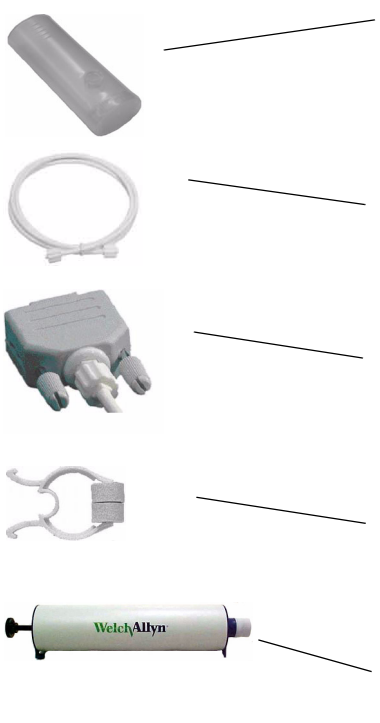
Product Overview

The CP 200 spirometry option performs FVC and SVC testing, including pre- and post-bronchodilator testing. It displays flow/volume and volume/time curves in real time, depicting both inspiratory and expiratory measurements.

For details, see the following sections:

- "Features" on page 5
- "Ordering Information for Replacement Parts" on page 9
- "Specifications" on page 55

Figure 1. Components of the CP 200 Spirometry Option



Disposable flow transducer
For single patient use. Eliminates the need for disinfecting procedures, which can be difficult and expensive. Minimizes the risk of cross-contamination.

Pressure tubing
Connects the flow transducer to the sensor.

Sensor
Connects to the CP 200 electrocardiograph. Converts pressure to air flow.

Nose clip
Recommended during testing to avoid leaks.

Three-liter calibration syringe
For daily use to calibrate the spirometer for accuracy.

Intended Use

The CP 200 spirometry option allows the user to acquire, view, store, and print measures and waveforms of pulmonary function including, but not limited to, maximal volume and flow of air that can be moved in and out of a patient's lungs. These measures are used in the diagnosis and monitoring of lung diseases and interventions for the treatment of certain lung diseases.

The spirometer may be used with patients who are able to understand the instructions for performing the test. However, normal values and interpretive results are not calculated for children under the age of six.

Indications for Use

Spirometry is indicated for use in various common clinical situations:

- Assessing health status before a patient begins strenuous physical activity.
- Evaluating the following symptoms, signs, or abnormal laboratory tests:

  Symptoms — dyspnea, wheezing, orthopnea, cough, phlegm production, chest pain

  Signs — diminished breath sounds, overinflation, expiratory slowing, cyanosis, chest deformity, unexplained crackles, shortness of breath

  Abnormal laboratory tests — hypoxemia, hypercapnia, polycythemia, abnormal chest radiographs

Contraindications

The spirometer does not support the MVV effort type.

Features

- Automatic interpretation and comparison of best pre-bronchodilator effort to best post-bronchodilator effort
- Real-time flow/volume and volume/time graphs on full-color LCD display
- Incentive graphic for pediatric patient coaching
- Multiple predictive adult norms, including NHANES III, and pediatric norms
- Reduced risk of cross-contamination with Welch Allyn single-use, disposable flow transducers
- Patient education help sheets
- Instant quality and variability checks for proper test performance
- Customizable report formats
- Independently validated to exceed the 1994 American Thoracic Society spirometry accuracy standards for both ambient and BTPS humidified air
- Single-flow and multiple-flow calibration protocols with automatic printing
- NIOSH, OSHA, and Social Security operation protocols to create reports that meet these agency requirements
- PCP (primary care practitioner) protocol that follows NLHEP guidelines
- Meets all industry standards, including ATS, NIOSH, OSHA, and Social Security
- Integrated into the CardioPerfect workstation for easy analysis, reviewing, storing, printing, and exporting

Symbols

The symbols illustrated here may appear on the spirometer components, on the packaging, on the shipping container, or in this manual.

Documentation Symbols	
	WARNING Indicates conditions or practices that could lead to illness, injury, or death.
	Caution In the documentation, this symbol indicates conditions or practices that could damage the equipment or other property.
	Caution On the product, this symbol means "Caution — consult accompanying documentation."

Operation Symbols			
	Spirometry key		Spirometry port
	Stacking limits		Do not reuse.
	Keep away from sunlight.		Expiration date
	Type BF applied part		

Using the Spirometer Safely

Before using or servicing the spirometer, you must read and understand the following safety-related information.

General Warnings

The following warning statements apply to spirometer use in general. Warning statements that apply specifically to particular procedures, such as preparing the patient for testing, appear in the corresponding sections of the manual.

Warning statements indicate conditions or practices that could lead to illness, injury, or death.

WARNING Do not perform spirometry tests if any of the following conditions apply to the patient:

- hemoptysis of unknown origin (forced expiratory maneuver may aggravate the underlying condition)
- pneumothorax
- unstable cardiovascular status (forced expiratory maneuver may worsen angina or cause changes in blood pressure)
- recent myocardial infarction
- pulmonary embolus
- thoracic, abdominal, or cerebral aneurysms (danger of rupture due to increased thoracic pressure)
- recent eye surgery (for example, cataract)
- presence of an acute disease process that might interfere with test performance (for example, nausea, vomiting)
- recent surgery of thorax or abdomen

WARNING The spirometer captures and presents data reflecting a patient's physiological condition. When reviewed by a trained physician or clinician, this data can be useful in determining a diagnosis. However, the data should not be used as a sole means for determining a patient's diagnosis.

WARNING To minimize chance of a misdiagnosis, it is the physician's responsibility to assure that spirometry tests are properly administered, evaluated, and interpreted.

WARNING To prevent the spread of infection, do not try to clean the flow transducers and nose clips. Discard these items after a single patient use.

WARNING Read and observe all safety information provided in the flow transducer instructions.

General Cautions

The following caution statements apply to spirometer use in general. Caution statements that apply specifically to particular procedures appear in the corresponding sections of the manual.

Caution statements indicate conditions or practices that could damage the equipment or other property.

Caution Do not clean the spirometer or any of its components. Trapped moisture in the pressure tubing or sensor could affect their accuracy. Replace the pressure tubing when it becomes dirty. Replace the sensor when it becomes faulty.

Caution Do not immerse any part of the spirometer into a cleaning liquid or sterilize it with hot water, steam, or air.

Caution Do not use aromatic hydrocarbons, rubbing alcohol, or solvents on the spirometer.

Caution If you choose to clean the calibration syringe, wipe its external surfaces as needed with a cloth dampened with water only.

Caution Use only parts and accessories supplied with the device and available through Welch Allyn. The use of accessories other than those specified may result in degraded performance of this device.

Caution When you put the spirometer away, store its pressure tubing in a basket or drawer or other place that prevents compression or kinking.

Caution Avoid installing the spirometer in direct sunlight or in a location where it may be affected by significant changes in humidity, ventilation, or airborne particles containing dust, salt, or sulfur.

Caution Keep the spirometer away from splashing fluids.

Ordering Information for Replacement Parts

Replace the following parts as noted:

- **flow transducers & nose clips** — Replace for each new patient.
- **pressure tubing** — Replace when dirty.
- **sensor** — Replace when faulty.

To order parts, call Welch Allyn. For phone numbers, see page ii.

Note Discard all spirometry components according to local regulations.

Item	Material Numbers	Quantity
Disposable flow transducers	703418 703419	25 100
Pressure tubing (2 meters)	703415	1
Sensor	703552	1
Nose clip	58550-0000	1
Calibration syringe (3 L)	703480	1
Germicidal Sani-Cloth® canister	26004-0000	1
Product information		
• *Spirometry Reference Chart* (wall poster)	71038-3000	1
• *Spirometry Effort Acceptability & Reproducibility* (wall poster)	703337	1
• *CP 200 Spirometry Option Quick Reference* (small card)	703977	1
• *CP 200 Spirometry Option Directions for Use*	703411	1
• CP 200 product information multi-language CD	401151	1

Getting Help

You can get help with the CP 200 spirometry option in a variety of ways beyond this manual.

- Press the Help key from the initial spirometry screen for a list of topics available to print.
- Review the other information that came with the spirometer. For list, see "Product information" on page 9.
- Contact Welch Allyn. For phone numbers, see page ii.

2 Reviewing the Spirometry Settings

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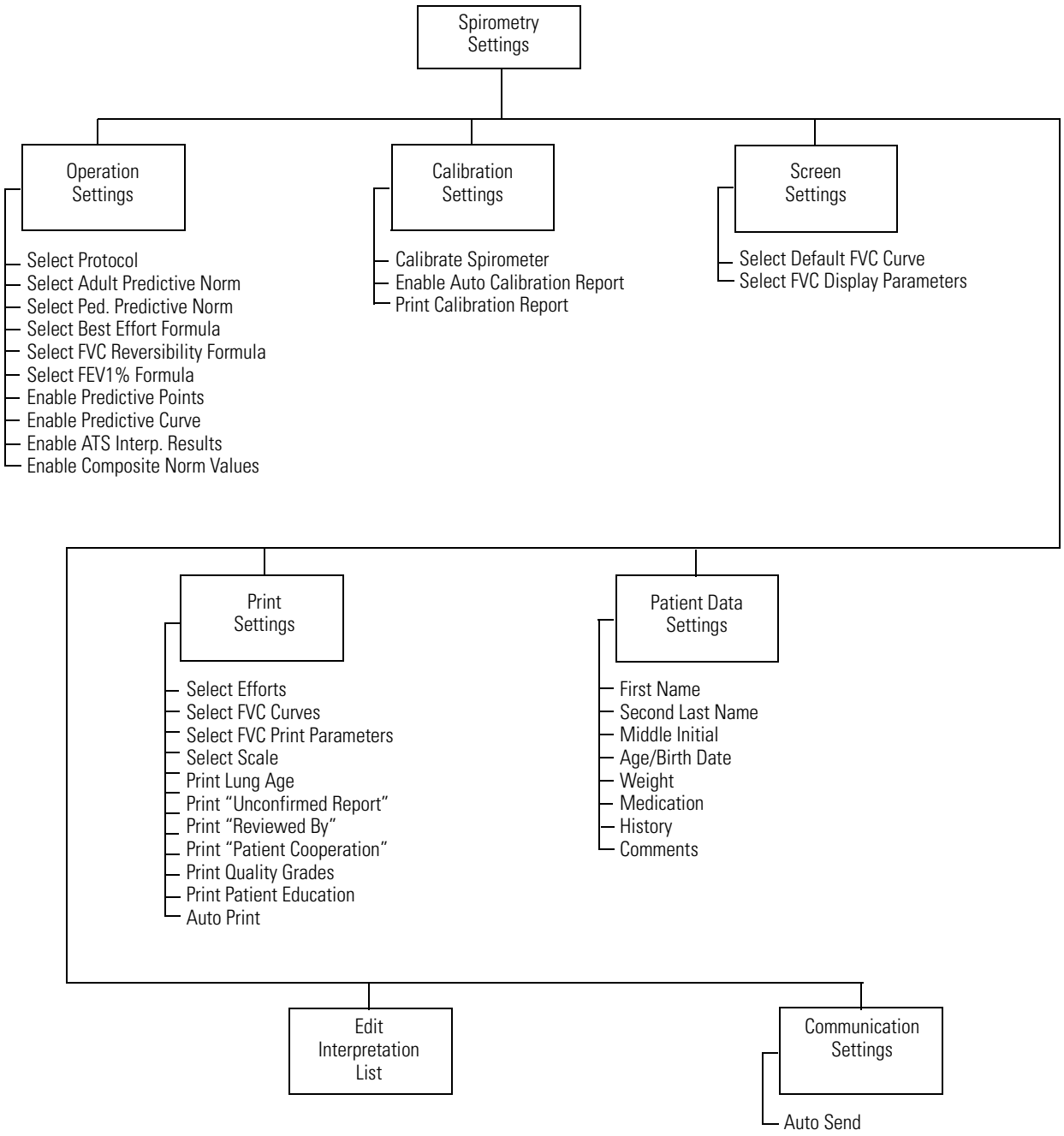
Note You can access the spirometry settings only if the spirometer is connected. See "Connecting the Spirometer Components" on page 39.

"Spirometry Settings" Menu Tree



Note:
As part of spirometry setup, you can also go to the **System Settings** > **Device Configuration** menu and select the following spirometry-related units of measure.

- **Flow:** L/sec or L/min (units for the y-axis on flow/volume curves)
- **Pressure:** mmHg, mbar, inHg, kPa (units for the calibration menu's atmospheric pressure values)
- **Temperature:** Fahrenheit or Celsius (units for the calibration menu's temperature values)

For details, see the electrocardiograph manual.

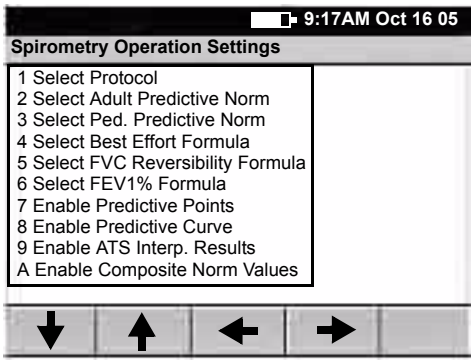
Reviewing the Operation Settings

To review or change the settings that affect the overall operation of the spirometer, reflected both on screen and in print, follow these steps.

1. Press the Menu key .
2. Choose **Spirometry Settings** > **Operation Settings**.

   The following screen appears.

Figure 2. "Spirometry Operation Settings" Screen


9:17AM Oct 16 05
Spirometry Operation Settings
1 Select Protocol
2 Select Adult Predictive Norm
3 Select Ped. Predictive Norm
4 Select Best Effort Formula
5 Select FVC Reversibility Formula
6 Select FEV1% Formula
7 Enable Predictive Points
8 Enable Predictive Curve
9 Enable ATS Interp. Results
A Enable Composite Norm Values

3. If desired, change the settings.

Setting	Description
Select Protocol	The selected protocol determines the way the spirometer operates when testing a patient. Applicable for FVC testing only. For details, see "Spirometry Protocols" on page 57. • None • PCP (primary care practitioner) • NIOSH • OSHA • SSD (Social Security & Disability)
Select Adult Predictive Norm	The selected adult norm is the primary source of predictive values for adult patients. For details, see "Norm Profiles" on page 68.
Select Ped. Predictive Norm	The selected pediatric norm is the primary source of predictive values for pediatric patients. For details, see "Norm Profiles" on page 68.
Select Best Effort Formula	A patient's best effort is a measurement calculated from a set of efforts. To determine the way in which best effort is calculated, choose from these options: • Best Measurement — Defines *best effort* as the single best effort in a set of efforts (best FVC-pre, best FVC-post, best SVC). This ATS-recommended method uses the effort with the highest sum of FVC + FEV1, or the effort with the highest SVC value. (For details, see the document noted in Reference 6 on page 76.) • Best Composite — Defines *best effort* as a composite of the highest parameter values across all selected efforts (except FVC and FEV1, which are both selected from the highest sum of FVC + FEV1.)

Setting	Description (continued)
Select FVC Reversibility Formula	Reversibility is the percentage difference between pre-test and post-test data for FVC testing. This measurement indicates the effect of medication on lung function. Reversibility applies to each parameter separately. To determine the way in which reversibility is calculated, choose from these options: • ((Post-Pre)/Pre)*100 • (Post/Pre)*100 • ((Post-Pre)/Predictive)*100
Select FEV1% Formula	The FEV1% formula determines the calculation method for a test's (not an effort's) overall FEV1% value, which affects the automatic interpretation. The variable part of this formula is the denominator. Both the numerator and the denominator represent *best effort* values. To determine the way in which FEV1% is calculated, choose from these options: • FVC (FEV1% = FEV1/FVC) • FIVC (FEV1% = FEV1/FIVC) • FEV6 (FEV1% = FEV1/FEV6) • Max (FVC, FIVC, SVC) (FEV1% = FEV1/FVC or FIVC or SVC, whichever is largest)
Enable Predictive Points	Yes or no. If yes, predictive points display and print. Predictive points may be enabled with or without the predictive curve. For details, see "predictive points" on page 80.
Enable Predictive Curve	Yes or no. If yes, a curve displays and prints along the predictive points. When the curve is enabled, the points are automatically also enabled.
Enable ATS Interp. Results	Yes or no. If yes, ATS interpretative results are included in the test record. For details, see "ATS interpretive results" on page 77.
Enable Composite Norm Values	Yes or no. If yes, any parameters that are not supported in the primary (selected) norm are given predictive values from alternative (composite) norm sources. If set to no, only the primary norm's values are used, no composite values. On the screen and in reports, any unsupported parameters appear without predictive values. For details, see "About Race Adjustment" on page 70.

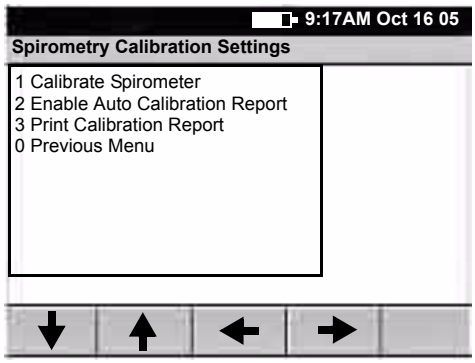
Reviewing the Calibration Settings

To review or change the settings that affect calibration — or to calibrate the spirometer — follow these steps.

1. Press the Menu key .
2. Choose **Spirometry Settings** > **Calibration Settings**.

   The following screen appears.

Figure 3. "Spirometry Calibration Settings" Screen



3. Change any desired settings.

Setting	Description
Calibrate Spirometer	Brings up the **Spirometer Calibration** screen. See "Calibrating the Spirometer" on page 23.
Enable Auto Calibration Report	Yes or no. If yes, a calibration report prints automatically every time you accept calibration results.
Print Calibration Report	Prints the most recent calibration report.

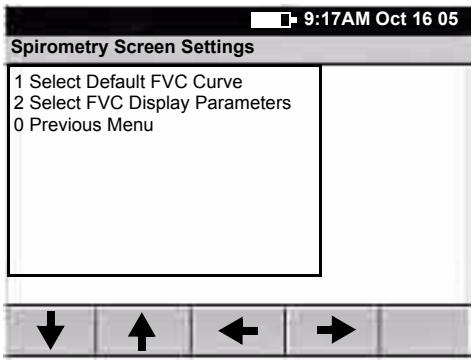
Reviewing the Spirometry Screen Settings

The spirometry screen is the first screen that displays after you enter patient data. For example, see Figure 29 on page 43. To review or change the settings for this screen, follow these steps.

1. Press the Menu key .
2. Choose **Spirometry Settings** > **Screen Settings**.

   The following screen appears.

Figure 4. "Spirometry Screen Settings" Screen



3. Change any desired settings.

Setting	Description
Select Default FVC Curve	Choices: volume/time, flow/volume, tidal volume, incentive. The selected default curve appears first whenever you begin FVC testing.
Select FVC Display Parameters	Choose which FVC-test parameters to display during testing. Choices (up to eight): FVC, FEV1, FEV1%, FEV6, PEF, FEF25-75, FEV0.5, FEV2, FEV3, FEV5, FEV1/FEV6, FEV0.5%, FEV2%, FEV3%, FEV5%, FEV6%, FEF25, FEF50, FEF75, FEF0.2-1.2, FEF75-85, FET, FIVC, FIV1, FIV1%, PIF, FIF50, FEF50/FIF50. Note: For SVC testing, these parameters always display: SVC, ERV, IRV, VT, BF, Tin/Tex.

Reviewing the Spirometry Print Settings

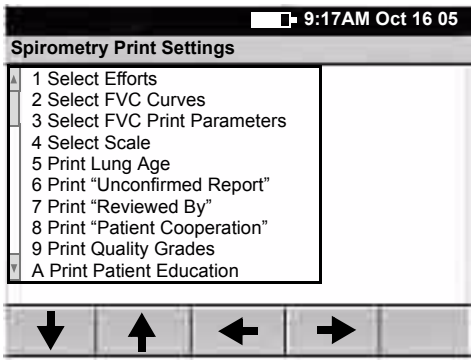
To review or change the settings that affect printed spirometry reports, follow these steps.

Note FVC and SVC efforts appear in separate print reports, even when they belong to the same test.

1. Press the Menu key .
2. Choose **Spirometry Settings** > **Print Settings**.

   The following screen appears.

Figure 5. "Spirometry Print Settings" Screen



3. Change any desired settings.

Setting	Description
Select Efforts	Choose which efforts are included in printed reports by default. If desired, when printing a test you can cycle through these choices and change the setting for that one test. • All efforts All efforts of each type performed. • Three best efforts The three efforts with the highest sum of FVC+FEV1. • Only best effort The best effort of each type performed To learn how to change the definition of *best effort*, see *"Select Best Effort Formula"* on page 13.

Setting (continued)	Description (continued)
Select FVC Curves	Choose which curve type to print for FVC efforts by default. If desired, you can change the curve type before you print. • volume/time • flow/volume • tidal volume • V/T & F/V (both volume/time and flow/volume) • V/T & display (when auto print is selected, prints both volume/time and the displayed curve type if flow/volume or tidal volume; incentive screens do not print.) • no curves Note: It is not necessary to select a default SVC curve for printing, because SVC curves are always volume/time.
Select FVC Print Parameters	Choose which FVC-test parameters to include in printed reports. You may select as many parameters as you like. If more are selected than fit on a page, the report continues to another page. Choices: FVC, FEV1, FEV1%, FEV6, PEF, FEF25-75, FEV0.5, FEV2, FEV3, FEV5, FEV1/FEV6, FEV0.5%, FEV2%, FEV3%, FEV5%, FEV6%, FEF25, FEF50, FEF75, FEF0.2-1.2, FEF75-85, FET, FIVC, FIV1, FIV1%, PIF, FIF50, FEF50/FIF50. Note: It is not necessary to select SVC print parameters, because they all print.
Select Scale	Choose which type of scaling (graph resizing) to use in printed volume/time curves. • Auto scale Graph is scaled to a small size. • 10 mm/s X axis (time) prints at 10 mm/s. Y axis prints at 10 mm/L. • 20 mm/s X axis (time) prints at 20 mm/s. Y axis prints at 10 mm/L.
Print Lung Age	Yes or no. If yes, the estimated lung age is included in printed reports for patients. For details, see "About Lung Age" on page 72.
Print "Unconfirmed Report"	Yes or no. If yes, "Unconfirmed Report" is included in printed reports.
Print "Reviewed By"	Yes or no. If yes, "Reviewed By _____" is included in printed reports, giving the clinician a place to sign.
Print "Patient Cooperation"	Yes or no. If yes, "Patient Cooperation _____" is included in printed reports, giving the clinician a place to comment.
Print Quality Grades	Yes or no. If yes, a test-quality grade is included in each printed report. See "About Test-Quality Grades" on page 74.
Print Patient Education	Yes or no. If yes, the patient help sheets on asthma and adult smoking prints automatically with every report. For examples of these sheets, see "Patient Help Sheets" on page 63.
Auto Print	Yes or no. If yes, a report prints automatically when you press the **Test Done** softkey.

Reviewing the Patient Data Fields Available

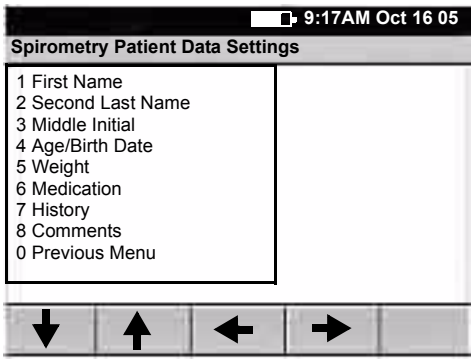
To review or change the fields that appear during data entry for spirometry patients, follow these steps.

Note You choose ECG data-entry fields separately, as described in the CP 200 electrocardiograph manual.

1. Press the Menu key .
2. Choose **Spirometry Settings** > **Patient Data Settings**.

   The following screen appears.

Figure 6. "Spirometry Patient Data Settings" Screen



Several fields — **Patient ID**, **Last Name**, **Height**, **Gender**, **Race**, and **Smoke Years** — always appear on the **Enter New Patient** screen, as shown in Figure 28 on page 41. Since these fields cannot be disabled or edited, they do not appear on this user-selectable list.

3. Change any desired settings.

   For most of these fields, you have two choices: on (enabled) or off (disabled). Disabled fields neither display nor print.

   You must choose either **Age** or **Birth Date**. This field cannot be disabled.

   For more details on these settings, see the description of patient data fields in the electrocardiograph manual.

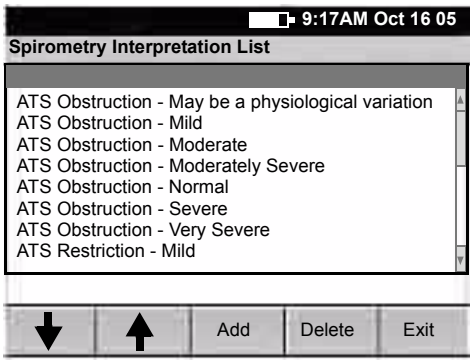
Reviewing the Interpretation List

To review or change the list of interpretative phrases that you can add to the interpretation area of the screen and reports, follow these steps.

1. Press the Menu key .
2. Choose **Spirometry Settings** > **Edit Interpretation List**.

   The following screen appears.

Figure 7. "Spirometry Interpretation List" Screen



3. Press the desired softkeys.

Softkey	Effect
Add	Lets you add statements to the list, up to a total of 50.
Delete	Deletes the highlighted statement.
Exit	Returns to the **Spirometry Settings** screen.

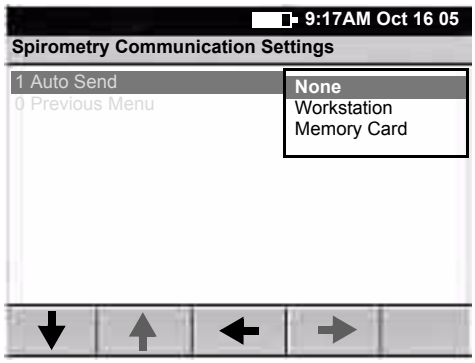
Reviewing the Auto Send Setting

To review or change the setting for automatically sending all spirometry test records to a CardioPerfect workstation or to an SD memory card, follow these steps.

1. Press the Menu key .
2. Choose **Spirometry Settings** > **Communication Settings** > **Auto Send**.

   The following screen appears.

Figure 8. "Auto Send" Submenu



3. If desired, change the setting.

   For details on these choices, see the CP 200 electrocardiograph manual.

Setting	Description
None	Test records are not automatically sent.
Workstation	All spirometry test records are automatically sent to a CardioPerfect workstation.
Memory Card	All spirometry test records are automatically sent to your SD memory card.

3 Calibrating the Spirometer

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About Calibration

The American Thoracic Society recommends calibrating a spirometer every day before testing. In addition, each time you open a new package of flow transducers, verify the lot number on the package label. If this lot number differs from the lot number used during the most recent calibration, you must recalibrate the spirometer before resuming testing.

There are two types of calibration:

- **Single-flow calibration**

  One inhale/exhale cycle.

- **Multiple-flow calibration**

  Three inhale/exhale cycles at three different rates:

  3 L in 1 second (3 L/s)
  3 L in 3 seconds (1 L/s)
  3 L in 6 seconds (0.5 L/s)

Note If you want to add efforts to a saved test, the calibration must stay the same. Whenever you recalibrate, you lose the ability to add new efforts to tests that were saved earlier.

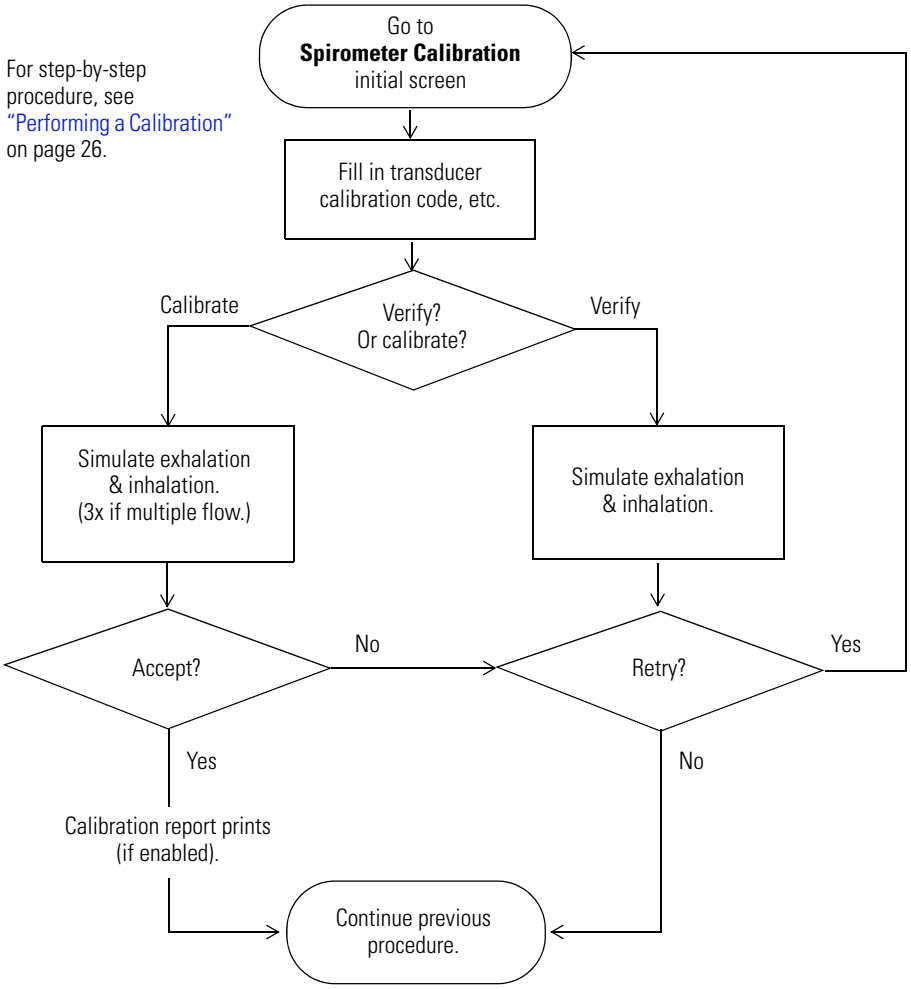
For a diagram illustrating this procedure, see Figure 9 on page 25.

For step-by-step calibration instructions, see "Performing a Calibration" on page 26.

For information on reviewing or changing the settings that affect calibration, see "Reviewing the Calibration Settings" on page 15.

Caution For proper performance, the calibration syringe itself must be recalibrated every year. See its calibration certificate for the most recent calibration date. When the syringe is due for recalibration, return it to the manufacturer. For details, see "Service Policy" on page 53.

Figure 9. Calibration, Process Diagram



Performing a Calibration

WARNING To avoid the risk of cross-contamination, always use a new flow transducer when calibrating the spirometer. Observe all safety information that came with the flow transducers.

Note When you open a new package of flow transducers, disregard the calibration CD that is shipped with them. The CP 200 spirometer does not use the calibration file on this CD.

1. Go to the **Spirometer Calibration** initial screen (Figure 10).

   You can get to this screen in either of two ways:

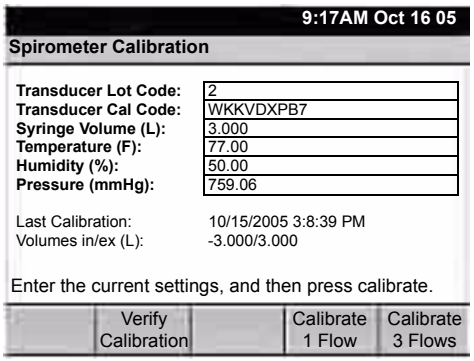
   - **At prompt**

     Press ✓ in response to the **Calibrate Now?** prompt, which appears the first time you press the Spirometry key each day (as described in Step 3 on page 41).

   - **Anytime**

     Press the Menu key, then choose **Spirometry Settings** > **Calibration Settings** > **Calibrate Spirometer**.

Figure 10. "Spirometer Calibration" Initial Screen

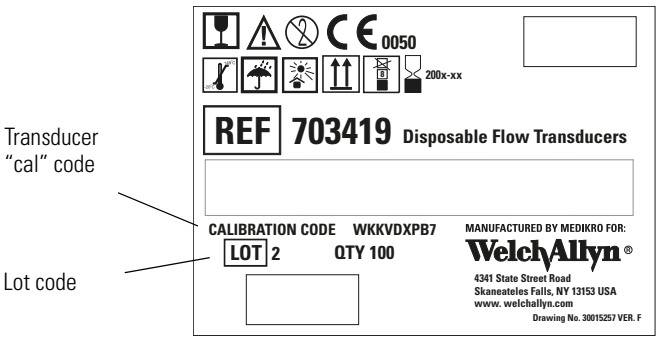


2. Fill in all fields.

   - Transducer lot and "cal" codes appear on the transducer package label, as shown in Figure 11.
   - For the syringe volume, see the sticker on the calibration syringe.
   - Update the temperature, humidity, and pressure. See your local weather reports.

   Note To learn how to change the pressure units, see page 12.

Figure 11. Calibration Code on Flow Transducer Package Label



3. Press the desired softkey, as listed here.

   - **Verify Calibration**

     To verify the accuracy of the system (without recalibrating).

   - **Calibrate 1 Flow**

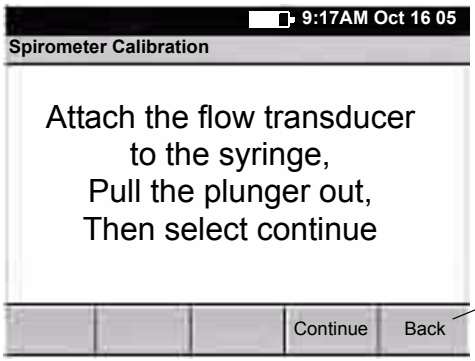
     To calibrate the system using one inhale/exhale cycle.

   - **Calibrate 3 Flows**

     To calibrate the system using three inhale/exhale cycles at three different rates.

The "attach flow transducer" prompt appears, as shown in Figure 12.

Figure 12. "Attach Flow Transducer" Prompt



At any time, you can press **Back** to return to the initial calibration screen, as shown in Figure 10 on page 26.

4. Connect a new flow transducer to the pressure tubing. See "Connecting the Spirometer Components" on page 39.

5. Attach the flow transducer to the syringe's port, shown here. Push the flow transducer all the way in for a tight seal.

Figure 13. Calibration Syringe

6. Pull the plunger all the way out.

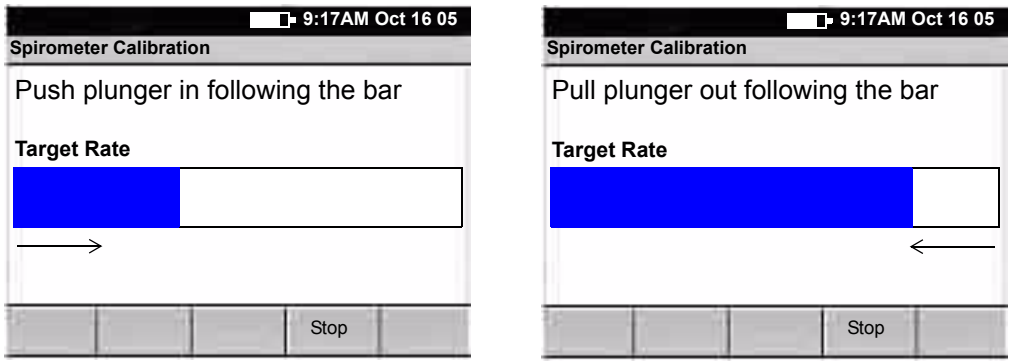
7. Press **Continue**.

Caution Several things may affect calibration results: movement of the syringe, movement of the pressure tubing, or blockage of air. Place the syringe on a hard, level surface with at least 1 cubic meter of open air surrounding the flow transducer. Place your hand on top of the syringe to prevent movement.

8. Press **Start**.

9. When the blue bar begins to move, push the plunger all the way in, then pull it all the way out, carefully following the bar's rate. Use a steady motion in both directions. See Figure 14.

Figure 14. Simulated Exhalation and Inhalation



If desired, you can press **Stop** any time. Softkeys will change, as described in Step 11 on page 30.

Otherwise, when no air has moved for three seconds, the following happens:

- **For verifications or single-flow calibrations**

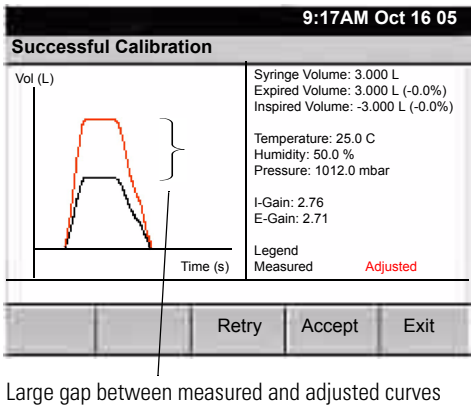
  The results display.

- **For multiple-flow calibrations**

  Another simulated exhalation screen appears. Repeat from Step 8 twice more. The results display.

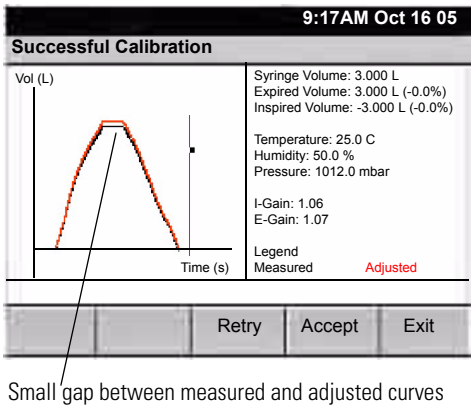
10. Review your results. See the following examples.

Figure 15. Poor Results, Single-Flow



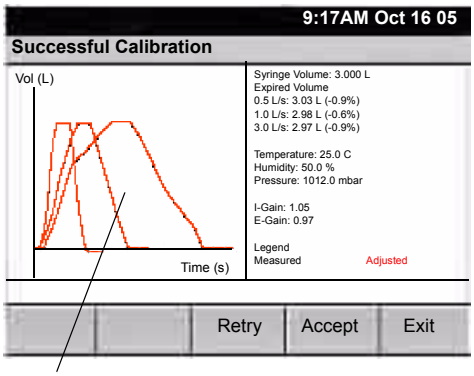
Large gap between measured and adjusted curves

Figure 16. Good Results, Single-Flow



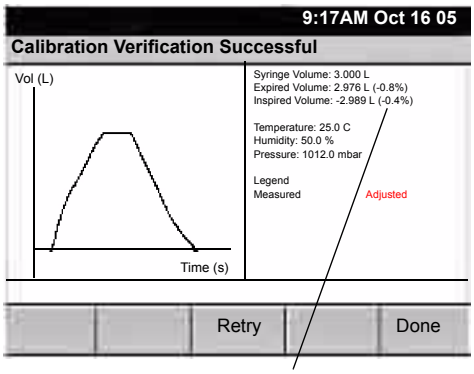
Small gap between measured and adjusted curves

Figure 17. Good Results, Multiple-Flow



No gap between measured & adjusted curves

Figure 18. Good Results, Verification



Error < 3%

11. Press the appropriate softkey.

Caution A poor calibration (as shown in Figure 15) indicates that the system had to make large adjustments to measure the syringe volume accurately. Do not accept poor calibrations, or your spirometry test results may be inaccurate.

- **Retry**

  Discards the results. Returns to initial calibration screen. Go to Step 2 on page 26.

- **Accept**

  Saves the results. Resumes your original procedure.

  If automatic report printing is enabled, a calibration report prints. To learn how to enable or disable automatic printing, see "Reviewing the Calibration Settings" on page 15.

- **Exit**

  Discards the results. Resumes your original procedure.

12. (Optional) Verify the most recent calibration — especially if your calibration results were questionable.

    a. Go back to Step 1 on page 26.

    b. Select **Verify Calibration** in Step 3.

    c. On your results screen, check the error percentages for the expired and inspired volumes. If <3%, your calibration is acceptable. If 3% or over, recalibrate. See example in Figure 18 on page 29.

Printing Calibration Reports

You can set up your system to print a calibration report automatically every time you accept calibration results. You can also print a report manually any time.

To Turn Automatic Report Printing On or Off

1. Choose **Spirometry Settings** > **Calibration Settings** > **Enable Auto Calibration Report.**
2. Select **Yes** or **No**.

To Print a Report Manually

Choose **Spirometry Settings** > **Calibration Settings** > **Print Calibration Report.**

4 Performing Spirometry Tests

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Connecting the Spirometer Components 39
Preparing the Patient 40
Recording a Test 41
Working With a Completed Test 45

Overview of the Testing Process

There are two types of spirometry efforts (also called maneuvers):

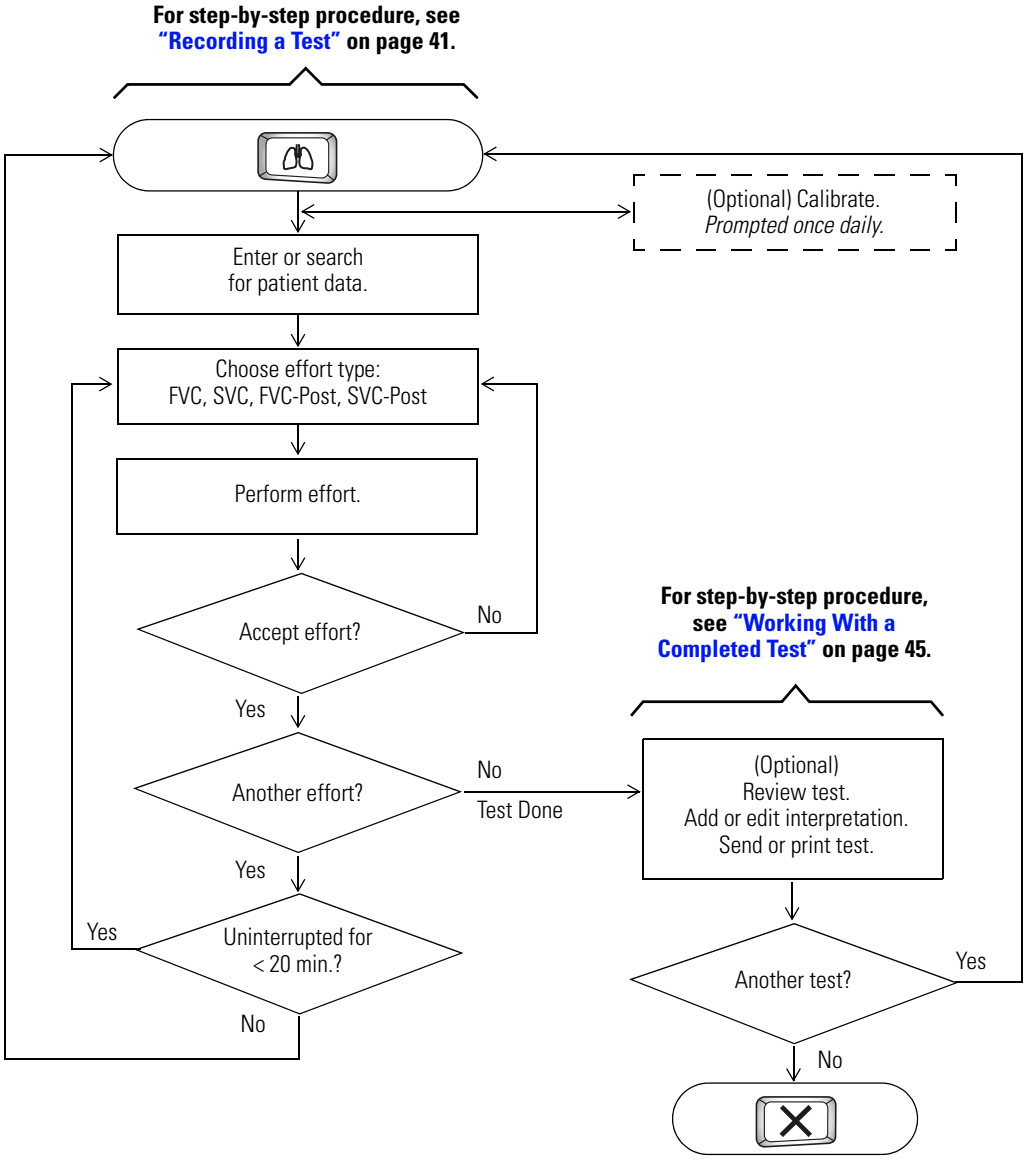
- FVC — forceful breathing
- SVC — relaxed breathing

For details, see "About FVC Efforts" on page 35 and "About SVC Efforts" on page 36.

A single test comprises a set of efforts — up to 6 efforts of each type (FVC and SVC) for a maximum of 12 efforts (6 FVC and 6 SVC). The 6 efforts of a given type can be a mixture of pre- and post-medication efforts.

For details, see "About Pre- and Post-Testing" on page 38 and "About Effort Replacement" on page 38.

Figure 19. Spirometry Testing Process Diagram



About FVC Efforts

"FVC" stands for forced vital capacity. The goal of an FVC effort is to measure the volume and flow of air. Patients inhale fully then exhale forcefully. Sometimes they also inhale forcefully.

When ready to begin an FVC effort, you coach the patient through these steps. (If preferred, you may reverse the order of inhaling and exhaling.)

1. Inhale fully — calmly fill your lungs as much as you can.
2. Place the flow transducer in your mouth.
3. Exhale forcefully — as fast as you can, as long as you can.
4. (Optional) Inhale forcefully — as fast as you can, as long as you can.

You can view and print FVC data in three types of curves, as shown in the following figures.

Figure 20. FVC Flow/Volume Curves

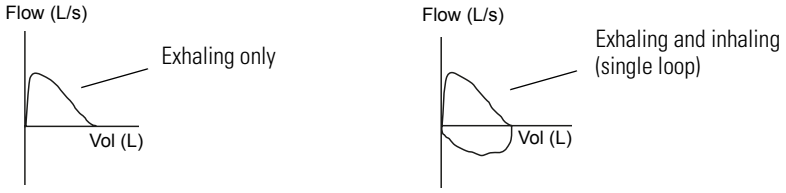


Figure 21. FVC Tidal Volume Curve

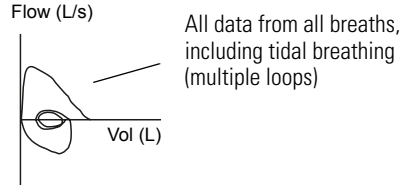
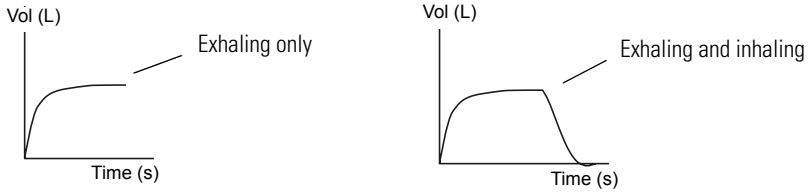


Figure 22. FVC Volume/Time Curves



During FVC testing, an animated incentive screen provides an alternative way to view the data (Figure 23). This screen gives patients, usually children, a fun goal to achieve while exhaling. (If the selected norm does not provide a valid FVC or PEF predicted value, the system tries to use the Polgar norm; if Polgar does not fit the patient's demographics, the incentive screen is not available.)

Figure 23. FVC Incentive Screen

About SVC Efforts

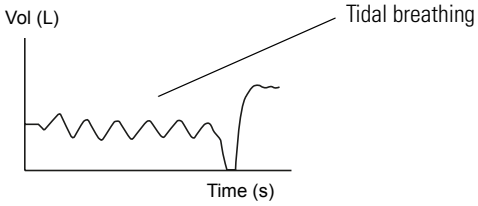
"SVC" stands for slow (relaxed) vital capacity. Sometimes SVC testing is used when forced breathing is impossible. The patient inhales and exhales as completely as possible, as in FVC testing, but the breathing is not forced. The goal of an SVC effort is to measure the volume of air inhaled and exhaled, not the air flow (speed).

When ready to begin an SVC effort, you coach the patient through these steps. (If preferred, you may reverse the order of inhaling and exhaling.)

1. Place the flow transducer in your mouth.
2. Breathe normally several times (tidal breathing).
3. Inhale fully — calmly fill your lungs as much as you can.
4. Exhale fully — calmly empty your lungs as much as you can.

The parameters measured during SVC testing are always displayed in a volume/time curve, as shown in Figure 24.

Figure 24. SVC Curve



About the Spirometry Parameters

During FVC and SVC testing, many parameters are measured and calculated. For definitions of these parameters, see "Glossary" on page 77.

During FVC testing, the two most important parameters in determining lung problems are FVC and FEV1. (For a description of how the automatic interpretation software uses these two measurements to determine the degree of obstruction or restriction, see "Understanding Your Interpretation Results" on page 75.)

- **FVC** — forced vital capacity, the maximum volume of air that can be forcibly and rapidly exhaled
- **FEV1** — forced expiratory volume 1, the volume of air that is exhaled at one second of a forced expiration

The following are important parameters for SVC testing:

- **VT** — tidal volume
- **ERV** — expiratory reserve volume
- **IC** — inspiratory capacity

About Pre- and Post-Testing

If desired, a spirometry test may include both pre- and post-efforts (FVC or SVC) to measure the effectiveness of medication. The "before medication" and "after medication" efforts may be uninterrupted or interrupted.

- **Uninterrupted**

  If there is no interruption between pre- and post-efforts (that is, no other patient has been tested and the electrocardiograph has remained on), the same screen continues to display. You simply continue with the procedure.

- **Interrupted**

  If there is an interruption (that is, another patient has been tested or the electrocardiograph has been turned off), you need to recall the patient's test-in-progress before continuing.

Note Pre- and post-efforts must happen on the same day, with the same calibration. The next day — or after a recalibration — tests become available for review only; you can no longer add efforts to them.

About Effort Replacement

You can save up to 6 FVC and 6 SVC efforts per test (maximum total of 12 efforts). After saving 6 efforts of a given type, the software compares each new effort with the saved efforts. If the new effort is better than the worst saved effort, the worst effort is deleted and the new one is saved. If the new effort is worse than all saved efforts, you are asked whether you want to save it.

If 6 pre-efforts have been saved, the worst pre-effort is deleted when you add a post-effort until you have saved 3 pre- and 3 post-efforts. After that, the "worst" post-effort is deleted.

Connecting the Spirometer Components

WARNING To prevent the spread of infection, use a new flow transducer for each patient. Use rubber gloves when replacing used flow transducers, and wash hands after touching them. Discard flow transducers after a single patient use.

1. Verify that the sensor and pressure tubing are clean and undamaged. Look for signs of deterioration, including but not limited to cracks, cuts, discoloration, or oxidation.

   If any part exhibits any of these symptoms, replace it. See "Ordering Information for Replacement Parts" on page 9.

2. Attach a flow transducer to the pressure tubing. See Figure 25.
3. Attach a sensor to the other end of the pressure tubing. See Figure 26.
4. Connect the sensor to the electrocardiograph's spirometry port. Hand-tighten the sensor connectors. Do not overtighten the connectors, or they may become stripped. See Figure 27.

   The CP 200 software automatically activates the spirometry functions throughout the software.

   Note Bacteria filters are unnecessary.

Figure 25. Attaching a Flow Transducer to the Pressure Tubing

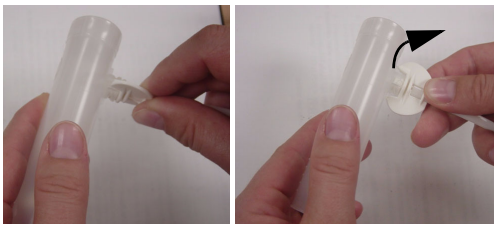


Figure 26. Attaching the Sensor to the Pressure Tubing

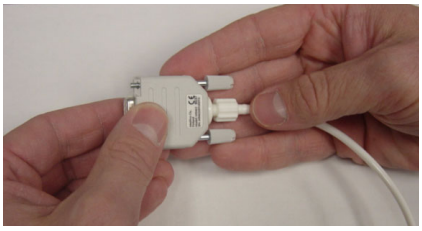


Figure 27. Connecting the Sensor to the Spirometry Port

Preparing the Patient

To prepare patients for any spirometry test, explain the entire procedure for the type of effort you want them to perform. Remind patients that the test is painless. Demonstrate at least one effort for the patient.

The accuracy of a spirometry test is highly dependent on the patient's understanding and cooperation. So, be prepared to coach and encourage the patient with your "body language" and your words — for example, "Blow, blow, blow, keep blowing until you can't blow any more out" — to ensure a good effort with reproducible results.

Instruct patients to do the following:

- Loosen any tight articles of clothing that might constrict lung function, for example, a tight belt, tie, vest, bra, girdle, or corset.
- Remove any foreign objects from the mouth, including loose dentures.
- Use of a nose clip is optional. Patients may also pinch their noses.
- Place your lips and teeth around a new transducer, sealing their lips tightly around the transducer. Grip slightly with your teeth in the groove. (If you need to hold the flow transducer in your hand, keep fingers away from the screen on the back.)
- Keep your tongue away from the flow transducer to avoid blocking it.
- Keep your chin up so as not to restrict the airway.

WARNING Patients may become faint, light-headed, dizzy, or short of breath during spirometry testing. Watch patients closely. If they choose to stand during testing, keep a chair immediately behind them. If there is any reason for concern, stop the test and take proper action.

WARNING Patients should not bite on the flow transducer. Biting could result in sharp edges, which could injure the mouth.

Recording a Test

To record a spirometry test, follow these steps.

1. Measure the patient's standing height to the nearest half inch (or centimeter) in stocking feet.

   Accuracy is important; height greatly influences the predicted values.

   Note If the patient has obvious spinal deformities, measure the arm span from fingertip to fingertip with arms outstretched against a wall. Enter the arm span instead of height.

2. If the patient's demographics do not match the current spirometry norm, select a more appropriate norm.

   To find out how, see "Select Adult Predictive Norm" on page 13 or "Select Ped. Predictive Norm" on page 13.

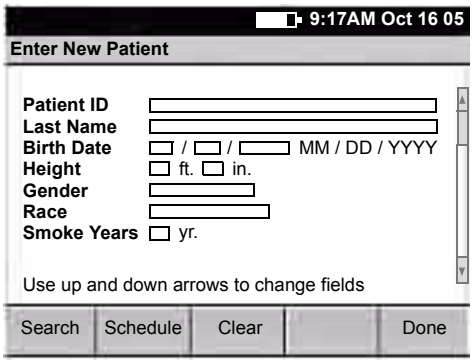
3. Press .

   The first time this key is pressed each day, the prompt "Calibrate Now?" appears.

4. (Optional) Calibrate. See "Calibrating the Spirometer" on page 23.

   The following screen appears.

Figure 28. "Enter New Patient" Screen



To learn how to choose which fields display here, see "Reviewing the Patient Data Fields Available" on page 19.

5. Enter or search for patient data.

a. To search for patient data

Press **Search** or **Schedule**, and select the patient. (For details, see CP 200 electrocardiograph manual.) Then press the desired softkey, as described here.

Softkey	Function	Your Next Action
New Test	Returns to the "Enter New Patient" screen with some data filled in.	Go to Step b, below.
Continue Test	Lets you continue a test-in-progress. This softkey appears only if it is the same day and the calibration is the same.	Go to Step 6 on page 43.
Review Test	Lets you recall any of that patient's saved tests and review its data. You cannot add new efforts, but you can edit the interpretation, send the test to an SD memory card or workstation, or print the test.	Go to "Working With a Completed Test" on page 45.

b. To enter patient data

Fill in the fields. All mandatory fields must be filled in before you can proceed.

Important Fields	Description
Patient ID, Last Name	Always mandatory. The patient must be identified.
Age/Birth Date, Height, Gender, Race	Always mandatory. This information determines the automatic interpretation.
Weight	Mandatory only when using Schoenberg or Hedenström norm.
Smoke Years	Not mandatory. If the patient smokes, enter the number of years the patient has smoked. If this value is 1 or more for an adult patient, and if patient education is enabled, the smoking help sheet prints after the spirometry test report. See "Patient Help Sheets" on page 63.

When finished entering data, press the desired softkey:

- **Clear** — deletes the patient data and returns to the **Patient ID** field.
- **Done** — accepts the patient data and goes to the initial spirometry screen.

6. Press **Effort Type** as needed to select the type of effort you want the patient to perform. See Figure 29.

   - FVC
   - FVC Post*
   - SVC
   - SVC Post*

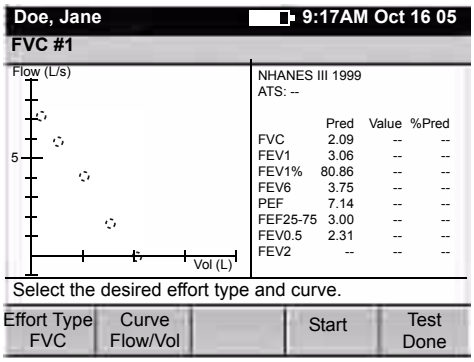
   *FVC Post and SVC Post are available only if you have already accepted at least one pre-effort of the same type.)

7. (FVC testing only) Press **Curve** as needed to select the curve type that you want to view while testing. See Figure 29.

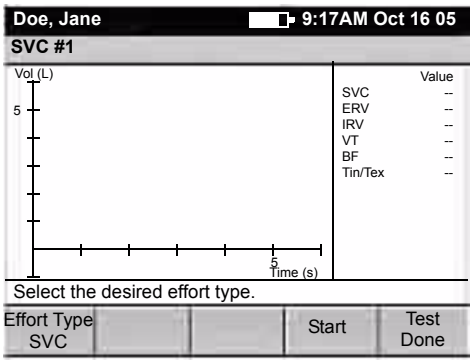
   - Flow/Volume
   - Volume/Time
   - Tidal Volume
   - Incentive

Figure 29. Spirometry Screen, Ready to Start Effort

FVC example (flow/vol curve)



SVC example

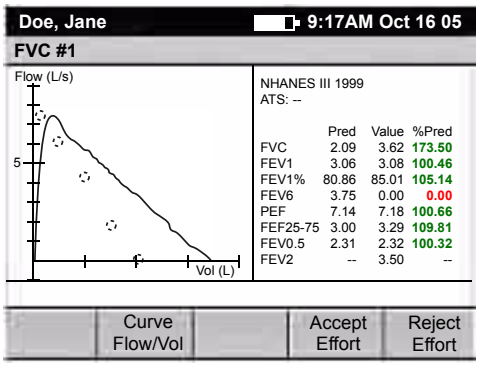


Note To learn how to change the default FVC curve type and parameters, see "Reviewing the Spirometry Screen Settings" on page 16.

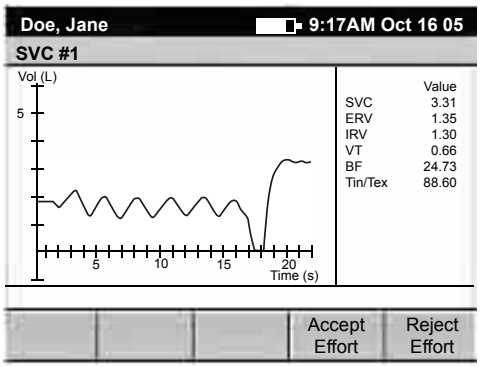
8. When ready, press **Start**.
9. Coach the patient through the effort. For tips, see "Preparing the Patient" on page 40.
10. When finished, press **Stop**.

Figure 30. "Effort Complete" Screen

FVC example (flow/vol curve)



SVC example



For FVC efforts, the "% predicted" values display in color as follows:

Red: % predicted values are below LLN.
Black: % predicted values are normal.
Green: % predicted values are at least 100%.

11. Review the data.

    For FVC tests, if desired, press **Curve** to alternate between curve types.

    Decide whether to accept the effort. For help deciding, see the *Spirometry Effort Acceptability & Reproducibility* poster.

    Note After each effort, a quality message appears on this screen, such as "Don't hesitate," "Blow out longer," or "Good effort." For details, see "About Effort-Quality Messages" on page 73.

12. Press the desired softkey.

    - **Accept Effort**

      Saves the effort. See "About Effort Replacement" on page 38.

    - **Reject Effort**

      Deletes the effort.

    In either case, the "ready to start effort" screen reappears (Figure 29 on page 43).

    Note The effort numbers increment with each new effort (FVC #1 becomes FVC #2, and so on), even if some efforts were deleted, so the test record indicates the patient's total number of efforts.

13. Determine your next step.

    - If you want to perform another effort, go to Step 6 on page 43.
    - If you are finished with this test, press **Test Done**.

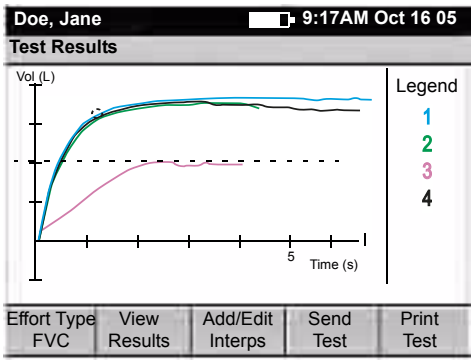
Working With a Completed Test

If you are looking at the **Test Results** main screen, shown here, you arrived here in either of two ways:

- You pressed **Test Done** after completing a set of efforts (Step 13 on page 44).
- You pressed **Review Test** to recall a saved test for review (Step 5 on page 42).

Figure 31. "Test Results" Main Screen

FVC example (vol/time curve)



All FVC curves, including any pre- and post-efforts, are displayed on one graph. Any SVC curves are displayed in a separate graph.

You are now ready to work with the completed test. Press the desired softkeys:

Softkey	Function
Effort Type	Alternates between FVC and SVC efforts, if applicable.
View Results	See "To View a Test's Results" on page 46.
Add/Edit Interp	See "To Change a Test's Interpretation Statements" on page 47.
Send Test	See "To Send a Test to an SD Memory Card or Workstation" on page 48.
Print Test	See "To Print a Test" on page 49.

When finished, determine what to do next.

- Press to start another test for this patient or another patient.

  Go to Step 3 on page 41.
- Press to exit spirometry mode.

To View a Test's Results

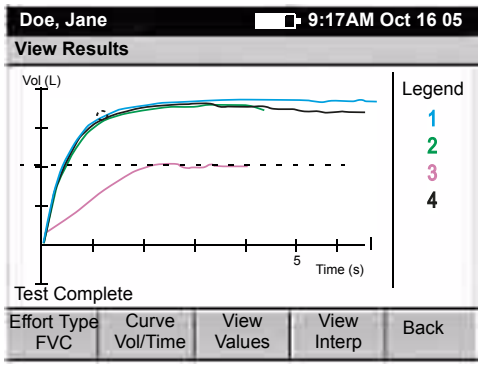
From the **Test Results** main screen (Figure 31 on page 45), follow these steps:

1. Press **View Results**.

   The display stays the same. Only the softkeys change, as shown here.

Figure 32. "View Results" Screen

FVC example (vol/time curve)



2. Press the desired softkeys to view the results in various ways.

Softkey	Function	Your Next Action
Effort Type	Alternates between FVC and SVC efforts, if applicable.	Press the next desired softkey.
Curve	Alternates between FVC curve types.	Press the next desired softkey.
View Values	Opens a window containing all of the measured and calculated parameters across all saved efforts — like a print preview. A test-quality grade appears too. For details, see "About Test-Quality Grades" on page 74. The best efforts and parameters display according to the print settings. See "Reviewing the Spirometry Print Settings" on page 17.	Press or to close the values window. Press the next desired softkey.
View Interp	Opens a window containing the interpretation statements that have been saved with the test. A test-quality grade appears too. For details, see "About Test-Quality Grades" on page 74.	Press or to close the interpretation window. Press the next desired softkey.
Back	Returns to the **Test Results** main screen, as shown in Figure 31 on page 45.	Return to "Working With a Completed Test" on page 45.

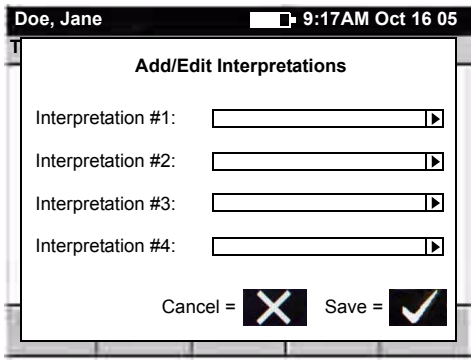
To Change a Test's Interpretation Statements

From the **Test Results** main screen (Figure 31 on page 45), follow these steps:

1. Press **Add/Edit Interps**.

   The following screen appears, displaying any interpretation statements that have been saved with the test.

Figure 33. "Add/Edit Interpretations" Screen



Press a right arrow key to see a list of interpretation statements that are available to choose for the highlighted field.

2. Add or edit interpretation statements as desired.

   Each test may include up to four statements — either automatically included, or manually added, or a combination. If automatic statements appear, you may replace them with manual statements if you wish.

3. Press to cancel or to save your changes.

   The **Test Results** main screen reappears, as shown in Figure 31 on page 45.

- To learn how to change the statements that are available to choose, see "Reviewing the Interpretation List" on page 20.
- To learn how to enable automatic interpretation, see "Enable ATS Interp. Results" on page 14.
- To learn how the automatic interpretation software determines the degree of obstruction or restriction, see "Understanding Your Interpretation Results" on page 75.

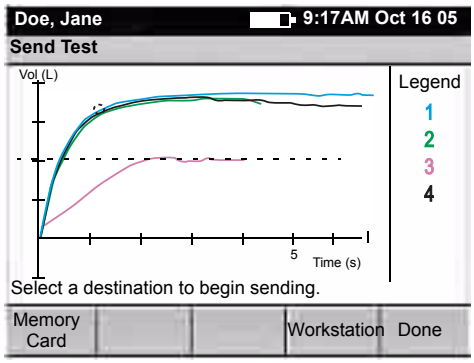
To Send a Test to an SD Memory Card or Workstation

From the **Test Results** main screen (Figure 31 on page 45), follow these steps:

1. Press **Send Test**.

   The following screen appears.

Figure 34. "Send Test" Screen



2. Select the desired destination.

   For details on these choices, see the CP 200 electrocardiograph manual.

   - **Memory Card**
   - **Workstation**

3. Press **Done**.

   The **Test Results** main screen reappears, as shown in Figure 31 on page 45.

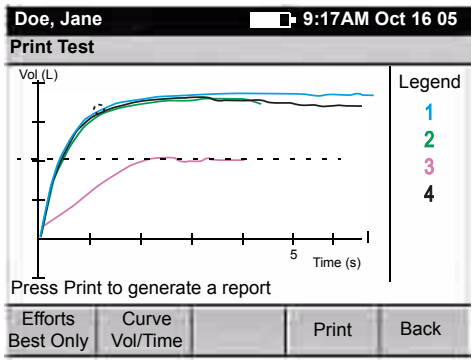
To Print a Test

From the **Test Results** main screen (Figure 31 on page 45), follow these steps:

1. Press **Print Test**.

   The following screen appears.

Figure 35. "Print Test" Screen



2. Press the desired softkeys.

Softkey	Function	Related Information
Efforts	Cycles through these print options: • **Best Only** Prints only the best effort of each type that was saved — best FVC, SVC, FVC-pre, FVC-post. • **3 Best** Prints the three best efforts of each type that was saved. • **All** Prints all efforts.	To change the default option, see "Reviewing the Spirometry Print Settings" on page 17. To change the definition of *best*, see "Select Best Effort Formula" on page 13.
Curve	Cycles through the curve types that are available to print: • Vol/Time • Flow/Vol • Tidal Vol • V/T and F/V • None	To change the default curve type for printed reports, see "Reviewing the Spirometry Print Settings" on page 17.
Print	Prints one copy of the test.	Press **Print** again for additional copies. FVC and SVC efforts print in separate reports. If "patient education" is enabled in the settings, one or more patient help sheets automatically print along with the test. For details, see "Patient Help Sheets" on page 63.
Back	Returns to the **Test Results** main screen.	See Figure 31 on page 45.

5 Troubleshooting

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Problem-Solving Suggestions

If you try these suggestions and still have problems, contact Welch Allyn. For phone numbers, see page ii.

Condition	Causes	Actions
When printing, text prints correctly but FVC curve does not.	Print settings	Make sure that the desired curve is selected. See "To Print a Test" on page 49.
Unable to calibrate.	• Poor connection between flow transducer and sensor. • Damage to flow transducer. • Leak during calibration. • Uneven calibration strokes.	• Check the connection between flow transducer and sensor. • Replace the flow transducer if it is damaged. • Ensure that the connection between the calibration syringe and flow transducer is tight with no leaks. • Use even strokes in calibration.
No sensor detected.	Poor connection between the sensor and the electrocardiograph.	Disconnect and reconnect the sensor.
Does not print.	• Out of paper. • Paper jam.	• Load paper. See the electrocardiograph manual. • If paper is jammed, clear it, then reload.
Values are too high (intermittent).	• Patient's fingers obstructed the screen on the back of the flow transducer, causing high back pressure and false reading. • Patient's lips were not tightly sealed around the flow transducer. • Spirometer was calibrated with the wrong size syringe.	• Retest. • Recalibrate with a 3-liter syringe. See "Calibrating the Spirometer" on page 23.
Values are too high (consistently).	Pressure connection is partially obstructed.	Remove any foreign substance from the flow transducer or pressure tubing.
Predictive values are blank.	• The selected norm does not support certain values, and composite norm values are disabled.	• Re-enter age/birthdate, height, gender, race. See Step b on page 42. • Enable composite norm values. See "Reviewing the Operation Settings" on page 13.
The flow sensor has been dropped.	Accident.	Recalibrate. See "Calibrating the Spirometer" on page 23.
Report does not print parameters or graphs.	Improper print settings.	Check print settings. See "Reviewing the Spirometry Print Settings" on page 17.
Patient test values differ from values expected by physician.	Various.	• If the transducer is contaminated with sputum or secretions, replace it. • Verify that proper barometric pressure has been entered. See "Calibrating the Spirometer" on page 23. • Verify the patient data. • Eliminate any leaks in the pressure tubing. • Retest using a nose clip. • Replace the sensor if damaged. • Recalibrate. • Replace the transducer and retest.

Limited Warranty

For general information on the limited warranty, see electrocardiograph manual.

The following spirometry components have specific warranty periods from date of shipment to customer:

- **Flow transducer** — 90 days
- **Pressure tubing** — 90 days
- **Sensor** — 12 months
- **Calibration syringe** — 12 months

Service Policy

For general information on the service policy, see electrocardiograph manual.

The following spirometry components have specific service policies. For disposable items, see "Ordering Information for Replacement Parts" on page 9.

- **Flow transducer** — Disposable.
- **Pressure tubing** — Disposable.
- **Sensor** — Return to Welch Allyn for replacement if necessary. Replacement is free within the warranty period.
- **Syringe** — Return to Welch Allyn for calibration verification if necessary. Recalibration is free within the warranty period. Beyond the warranty period, return to the manufacturer:

  AM Systems, Inc.
  131 Business Park Loop
  Carlsborg, WA 98324
  (800) 426-1306

A Specifications

Feature	Specification
Dimensions & weights	
Flow transducer	2.4 x 2.4 x 2 in. (6 x 6 x 5 cm) 0.4 oz (12 g)
Pressure tubing	2.2 yd (2 m) 0.9 oz (25 g)
Sensor	2.2 x 1.4 x 0.6 in. (5.4 x 3.4 x 1.6 cm) 0.9 oz (25 g)
Tests	FVC, SVC, pre- and post-bronchodilator
Flow technology	Pneumotach
Power equipment	Powered by CP200 electrocardiograph via serial port (no battery)
Power consumption	5 to 15 mA
Accuracy	Meets or exceeds 1994 ATS standard
Reproducibility	Meets or exceeds 1994 ATS standard
Flow range	0–14 L/s
Predictive norms	
Adult	Berglund 1963, Crapo 1981, ECCS / Quanjer 1993, Gulsvik 2001, Hedenström 1986, Knudson 1976, Knudson 1983, Kory 1961, Morris 1971, NHANES III 1999, Schoenberg 1978, Viljanen 1981
Pediatric	Berglund 1963, Dockery 1983, Hsu 1979, Knudson 1976, Knudson 1983, Koillinen 1998, NHANES III 1999, Polgar 1971, Schoenberg 1978, Solymar 1980, Zapletal 1969
Interpretation	1991 ATS interpretation standards. Lung age calculation can be enabled or disabled. Automatic interpretation can be enabled or disabled. User-definable interpretation statements are also available to be added manually.
Reports	
FVC testing	Volume/time curve Flow/volume curve Tidal volume Both volume/time and displayed curves No curves
SVC testing	Volume/time curve No curve

Feature (continued)	Specification (continued)
Parameters	
FVC testing	FVC, FIVC, FIV1, FIV1%, FEV0.5, FEV1, FEV2, FEV3, FEV5, FEV6, FEV1/FEV6, FEV0.5%, FEV1%, FEV2%, FEV3%, FEV5%, FEV6%, PEF, FEF25, FEF50, FEF75, FEF0.2-1.2, FEF25-75, FEF75-85, PIF, FIF50, FEF50/FIF50, FET
SVC testing	SVC, ERV, IRV, VT, IC, BF, MV, Tin, Tex, Tin/Tex
Quality checks	Effort acceptability and test reproducibility checks. Effort-quality messages and test-quality grades. Audio and visual incentive for assistance in coaching patients.
Connectivity	Compatible with CardioPerfect workstation.
Protection against ingress of water, per IEC 60529 (spirometry components)	IPX0
Protocols	PCP (primary care practitioner) NIOSH OSHA SSD (Social Security & Disability) None

Specifications are subject to change without notice.

B Spirometry Protocols

About the PCP Protocol 58
About the NIOSH Protocol 60
About the OSHA / Cotton Dust Protocol 61
About the SSD Protocol 62

This appendix describes the protocols you can select to change the way the CP 200 spirometer operates when testing a patient. Any features that are not specified in the protocol use your own settings.

To learn how to review or change the protocol, see "Select Protocol" on page 13.

About the PCP Protocol

The PCP (primary care practitioner) protocol is for users who want to make sure that testing meets the requirement of the National Lung Health Education Program (NLHEP). When the PCP protocol is selected, the spirometer automatically performs as described here, regardless of user-defined settings.

For details on PCP requirements, see the document noted in Reference 1 on page 76.

When this protocol is selected, testing and reports are affected as follows:

- **Operation Settings**

  Adult Predictive Norm: NHANES III
  Ped. Predictive Norm: NHANES III
  Best Effort Formula: Best Measurement
  Reversibility Formula: (Post-Pre)/Pre x 100
  FEV1% Formula: FEV6
  Predictive Points: YES
  Predictive Curve: YES
  ATS Interpretation Results: NO
  Composite Norm Value: NO
  Automatic Quality Check: NO

  (For details, see "Reviewing the Operation Settings" on page 13.)

- **Screen Settings**

  FVC Display Parameters: FEV1, FEV6, and FEV1/FEV6 only

  (For details, see "Reviewing the Spirometry Screen Settings" on page 16.)

- **Print Settings**

  Efforts: Only Best Effort
  FVC Curves: V/T & F/V
  FVC Print Parameters: FEV1, FEV6, and FEV1/FEV6 only
  Scale: 20 mm/s & 10 mm/L
  Print Lung Age: YES
  Print "Unconfirmed Report": YES
  Print "Reviewed By": YES
  Print "Patient Cooperation": YES
  Print Quality Grades: YES
  Print Patient Education: YES
  Auto Print: YES

  (For details, see "Reviewing the Spirometry Print Settings" on page 17.)

Post results are compared (%c column) to the pre results only if the test-quality grades for both pre- and post-test sessions are A, B, or C.

An ATS interpretation is displayed and printed only if the test session pre and post quality grades are A, B, or C.

If the pre or post quality grades are D or F, interpretation states "results should be interpreted with caution."

If the pre or post quality grade is D and the results are within normal limits, the interpretation states, "normal, but the reported FEV1 and FVC should not be used for comparisons with previous or subsequent tests."

Interpretation states "airway obstruction" when the FEV1/FEV6 is below the LLN.

Interpretation states "low vital capacity, perhaps due to restriction of lung volumes" if FEV1/ FEV6 is above the LLN, but the FEV6 is below the LLN.

Note When PCP protocol is selected, no inspiration is recorded.

About the NIOSH Protocol

The NIOSH (National Institute for Occupational Safety and Health, U.S.) protocol is for users who want to make sure that occupational testing and reports meet the requirements of NIOSH. The device automatically performs as described here, regardless of user-defined settings.

When using this protocol, the spirometer should be calibrated at three different flows every day before use.

For details on NIOSH requirements, see the document noted in Reference 4 on page 76.

When this protocol is selected, testing and reports are affected as follows:

- **Operational Setting**

  Adult and Pediatric Norm: NHANES III
  (For Asian-Americans the reference equations for Caucasians shall be used, but a correction factor of 0.94 shall be applied to the predicted values.)

  Best Effort Formula: Best Measurement

  Composite Norm Values: NO

  (For details, see "Reviewing the Operation Settings" on page 13.)

- **Print Settings**

  Tests: Three Best Efforts
  Scale: 20 mm/s & 10 mm/L
  Curves: V/T & F/V
  Auto Print: YES

  (For details, see "Reviewing the Spirometry Print Settings" on page 17.)

- **Calibration Settings**

  Auto Calibration Report: Yes

  (For details, see "Reviewing the Calibration Settings" on page 15.)

About the OSHA / Cotton Dust Protocol

The OSHA (Occupational Safety & Health Administration, U.S.) Cotton Dust protocol is for users who want to make sure that occupational testing and reports meet the requirements of OSHA's Cotton Dust standard. The device automatically performs as described here, regardless of user-defined settings.

When using this protocol, the spirometer should be calibrated at three different flows every day before use.

For details on OSHA / Cotton Dust requirements, see the document noted in Reference 8 on page 76.

When this protocol is selected, testing and reports are affected as follows:

- **Operational Settings**

  Adult and Pediatric Norm: Knudson 1976
  (African-American patients shall be adjusted by 0.85. Asian and Hispanic patients shall be adjusted according to General Norm Value Race Adjustment logic.)

  Composite Norm Values: NO

  (For details, see "Reviewing the Operation Settings" on page 13.)

- **Print Settings**

  Tests: Three Best Efforts
  Scale: 20mm/s & 10mm/L
  Curves: V/T & F/V

  (For details, see "Reviewing the Spirometry Print Settings" on page 17.)

About the SSD Protocol

The SSD (Social Security Disability) protocol is for users who want to make sure that testing associated with disability determinations meet the requirement of the Social Security Administration. The device automatically performs as described here, regardless of user-defined settings.

For details on SSD requirements, see the document noted in Reference 2 on page 76.

When this protocol is selected, testing and reports are affected as follows:

- **Calibration Settings**

  Auto Calibration Report: Yes

  (For details, see "Reviewing the Calibration Settings" on page 15.)

- **Print Settings**

  Tests: Three Best Efforts
  Scale: 20mm/s & 10mm/L
  Curves: V/T & F/V

  (For details, see "Reviewing the Spirometry Print Settings" on page 17.)

- Calibrations must be presented in a volume-time format at a speed of at least 20 mm/sec and a volume excursion of at least 10 mm/L to permit independent evaluation.
- Two of the satisfactory efforts should be reproducible for both pre-bronchodilator tests and, if indicated, post-bronchodilator tests.
- A test is considered reproducible if the two best efforts' FVC and FEV1 do not differ by more than 5 percent or 0.1 L, whichever is greater.
- An effort is satisfactory for measurement of the FEV1 if the expiratory volume at the back-extrapolated zero time is less than 5 percent of the FVC or 0.1 L, whichever is greater.
- An effort is satisfactory for measurement of the FVC if maximal expiratory effort continues for at least 6 seconds.
- The device should accurately measure time and volume, the latter to within +/- 1% of a 3 L calibrating volume.
- The testing device must have had a recorded calibration performed previously on the day of the measurement.
- The linearity of the device must be documented by recording volume calibrations at three different flow rates of approximately 3 L/6 sec, 3 L/3 sec, and 3 L/sec.
- These calibrations may be exhale-only since no inhale parameters are reported.
- Whenever the test report is printed, the calibration report shall also be printed.
- If the calibration accuracy is between 1% and 3%, the electrocardiograph applies correction factors to the recorded FVC and FEV1.

C Patient Help Sheets

About the Patient Help Sheets 64
Adult Smokers Help Sheet 65
Asthma Symptoms Help Sheet 66

About the Patient Help Sheets

Two patient help sheets are available to print:[1]

- **Adult Smokers**

  If "patient education" is enabled, the Adult Smokers sheet prints automatically for all adult smokers whenever you print a test. For example, see "Adult Smokers Help Sheet" on page 65.

- **Asthma Symptoms**

  If "patient education" is enabled, the Asthma Symptoms sheet prints automatically for all patients whenever you print a test. For example, see "Asthma Symptoms Help Sheet" on page 66.

These help sheets print only if "patient education" is enabled in the settings. To learn how to enable "patient education," see "Reviewing the Spirometry Print Settings" on page 17.

The patient's name, FEV1%, and date print automatically on both sheets. If "ATS Interpretation" is enabled, the appropriate recommendation is also marked. To learn how to enable "ATS Interpretation," see "Reviewing the Operation Settings" on page 13.

Note If no recommendation is marked, the doctor must mark one.

1. Both help sheets come from a booklet entitled *Simple Office Spirometry for Primary Care Practitioners,* by Thomas L. Petty, MD, and Paul L. Enright, MD. This booklet can be downloaded from the National Lung Health Education Program (NLHEP) home page: www.nlhep.org/resources.html.

Adult Smokers Help Sheet

Name _____

What Your Lung Function Results Mean For Adult Smokers

You have just performed Spirometry, the basic test of how well your lungs are working. The results indicate whether you have developed chronic obstructive pulmonary disease (COPD) due to smoking. COPD occurs in about one of every five smokers after more than 20 years of smoking. COPD slowly "eats away" at the lung's reserves. Affected smokers are often unaware of lung disease until more than half of their lung function has been lost. Spirometry testing can detect COPD many years before symptoms occur.

___ Your test result was within the normal range. You do not appear to be developing COPD. However, as a smoker, you remain at high risk of developing a heart attack, stroke, and/or lung cancer. Call the number at the bottom of this page for help with smoking cessation.

___ Your test result shows mild airways obstruction, suggesting that you are a "susceptible smoker" who already shows signs of early COPD. You are unable to blow out air as quickly as normal (your FEV1/FVC is low). If you continue smoking, you will eventually develop disabling lung disease (in about 10-20 years). If you are able to successfully quit smoking sometime soon, your lung function may return to normal levels and you will probably never develop symptoms of COPD. Call the number at the bottom of this page if you would like information about local resources to help you quit smoking.

___ Your test result shows moderate-to-severe airways obstruction. You have COPD. If you continue smoking, your lung disease will certainly get worse and you will eventually become short of breath while walking, climbing stairs, or doing other exercise. It is very important that you seek help to stop smoking. If you are able to successfully quit smoking sometime soon, you will probably regain a little lung function within three months, and the abnormally rapid decline in your lung function which you have experienced due to smoking will be stopped. Call the number at the bottom of this page for information about local resources to help you quit smoking.

___ Your test shows a low forced vital capacity (FVC). Your FVC is the total amount of air that you exhaled, in liters (similar to quarts). Values below about 80% are abnormally low and suggest that you are unable to inhale or exhale as much air as most healthy persons of your age, height, gender, and race. Obesity may be one of the causes of a mildly decreased FVC, and pneumonia is another. Consider asking your physician to review this report at some time during the next couple of months.

Your result: _____ FEV1 % predicted

For more information contact:

_____

Date

Asthma Symptoms Help Sheet

Name _____

What Your Lung Function Results Mean For Those With Symptoms Suggesting Asthma

You have just performed Spirometry, the basic test of how well your lungs are working. The results may indicate whether you have asthma and its severity.

___ Your test was within the normal range. If you recently had symptoms such as episodes of shortness of breath with wheezing, chest tightness, or cough, you may have asthma, but your lung function is normal today. Consider visiting a physician when you again have asthma symptoms and then repeat this Spirometry test. If you already know that you have asthma, it is in good control.

___ Your breathing test shows mild airways obstruction (some narrowing of your breathing tubes). You are currently unable to blow out air quickly. This result may indicate asthma that is not well controlled. Discuss with your physician medications to better control your asthma.

___ Your breathing test shows moderate-to-severe airways obstruction (narrowing of your breathing tubes). You are currently unable to blow out air quickly. This result usually indicates asthma that is poorly controlled. Discuss with your physician very soon the use of medications that will help to better control your asthma and the value of peak flow monitoring.

___ Your test shows a low forced vital capacity (FVC). Your FVC is the total amount of air that you exhaled, in liters (similar to quarts). Values below about 80% are abnormally low and suggest that you are unable to inhale or exhale as much air as most healthy persons of your age, height, gender, and race. Obesity may be one of the causes of a mildly decreased FVC, and pneumonia is another. Consider asking a physician to review this report at some time during the next couple of months.

Your result: _____ FEV1 % predicted

Your peak flow after inhaling a bronchodilator was _____ L/s (liters per second). You can compare this value to the peak flow that you measure using your own peak flow meter. The two numbers should match within 1 L/s. If your asthma is currently in good control, today's value may be close to your best peak flow reading at home.

_____

Date

D Predictive Norms, etc.

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Norm Profiles

Each predictive norm supports a particular subset of parameters and covers a particular population, as shown here.

	Parameters Studied															Gender		Age					Race			
Norm Name (Abbrev.)	FVC	FEV1	FEV1%	FEV0.5	FEV3	FEV3/FVC	FEV6	FEV1/FEV6	PEF	FEF25-75	FEF75	FEF50	FEF25	FEF0.2-1.2	FEV0.5%	Male	Female	Pediatric	Adult	Height (cm)	Weight (kg)	Smoke Years	Caucasian	Black	Hispanic	Asian
Berglund 1963 (be)	X	X	X													X	X	≥ 7	≤ 70				X			
Crapo 1981 (cr)	X	X	X	X	X	X				X						X	X	No	M: 15–91 F: 17–84				X			
Dockery 1983 (do)	X	X														X	X	6–11	No	110–160			X	X		
ECCS/Quanjer 1993 (qu)	X	X	X						X	X	X	X	X			X	X	No	18–70	M: 155–195 F: 145–180			X	X		X
Gulsvik 2001 (gu)	X	X	X						X	X						X	X	No	M: 15–91 F: 17–84	M: 157–194 F: 146–178			X			
Hedenström 1986 (he)	X	X	X						X		X	X	X			X	No	No	20–70	160–196	55–109	5–55	X			
Hsu 1979 (hs)	X	X							X	X						X	X	7–20	No	M: 111–200 F: 111–180			X	X	X	
Knudson 1976 (k)	X	X	X							X	X	X				X	X	≥ 8	≤ 90				X			
Knudson 1983 (kn)	X	X	X							X	X	X				X	X	≥ 6	M: ≤ 85 F: ≤ 88	M: 111.8–195.6 F: 106.7 –182.9			X			
Koillinen 1998 (kl)	X	X	X	X					X			X			X	X	X	6–16	No				X			
Kory 1961 (ko)	X	X		X												X	No	No	18–66				X			
Morris 1971 (mo)	X	X								X				X		X	X	No	20–84				X			
NHANES III (nh)	X	X	X				X	X	X	X						X	X	≥ 8	≤ 80				X	X	X	
Polgar 1971 (po)	X	X						X	X							X	X	3–19	No	110–170			X			
Schoenberg 1978 (sc)	X	X	X						X		X	X				X	X	≥ 7	≥ 18		11.7 – 137.2		X	X		
Solymar 1980 (so)	X	X							X		X	X	X			X	X	7–18	No				X			
Viljanen 1981 (vi)	X	X	X						X			X	X			X	X	No	18–65				X			
Zapletal 1969 (za)	X	X							X		X	X	X			X	X	6–18	No	M: 118–181 F: 107–173			X			

List of Norm-Related Clinical Studies

Each of the following studies provides expected values for various spirometric parameters by measuring significant samples of a particular population.

Norm	Clinical Study
Berglund 1963	*Reference Spirometric Studies in Normal Subjects: Forced Expiratograms in Subjects 7-70 Years of Age*, Berglund, et. al., Acta Medica Scandinavica, volume 173, 1963.
Crapo 1981	Reference Spirometric Values using Techniques and Equipment that Meet ATS Recommendations, Crapo, et. al., American Review of Respiratory Disease 1981, 123:659-664.
Dockery 1983	*Distribution of Forced Vital Capacity and Forced Expiratory Volume in One Second in Children 6-11 Years of Age*, Dockery, et. al., American Review of Respiratory Disease 1983, 128:405-412.
ECCS/Quanjer 1993	*Lung Volumes and Forced Ventilatory Flows: Official Statement of the European Respiratory Society*, Quanjer, et. al., European Respiratory Journal, 1993, supplement 16: 5-40.
Gulsvik 2001	*Forced Spirometry Reference Values for Norwegian Adults: The Bronchial Obstruction in Nord-Trondelag Study*, Langammer, Gulsvik , et. al., European Respiratory Journal 2001, 18: 770-779.
Hedenström 1986	*Reference Values for Lung Function Tests in Men: Regression Equations With Smoking Variables*, Hedenström, et. al., Upsala Journal of Medicine Science 91:299-310, 1986.
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About Norm Extrapolation

Extrapolation is the practice of applying a norm's formula to a patient who doesn't fit that norm's demographics. For example, if you were testing an 88-year-old man, and the primary (selected) norm were based on males 85 or younger, the predicted values would be extrapolated values.

- When it takes place, extrapolation is indicated in the test record.
- Pediatric norms do not provide any age, weight, or height extrapolation.
- Adult norms allow extrapolation of age up, but not down.
- Adult norms allow extrapolation of height, weight, and smoke years, up and down.

About Race Adjustment

Although expected values for certain parameters vary significantly between ethnic groups, some norm studies do not include separate regression equations for different races. For those studies, the following table describes the adjustments made by the CP 200 software for the FVC and FEV1 predicted values. Where applicable, norm values are multiplied by the percentages identified in the following table.

Race Choices	FVC & FEV1	Recommendation Source
Caucasian	No adjustment	—
Black	88%	ATS
Asian	94%	NIOSH
Hispanic	No adjustment	None found

Note Race adjustment applies for adults only.

If a race adjustment percentage is used, the same adjustment is applied to the LLN value.

About Composite Norm Values

When the primary (selected) norm does not support a given parameter — and when composite norm values are enabled in the operation settings — the missing value is filled in from one of the alternative (composite) norm sources, listed here. For example, since the Crapo norm does not support FEV6, this value is filled in from NHANES III.

Composite Norm Source	Parameters Filled In When Not Supported in Primary Norm
NHANES III	FVC, FEV1, FEV1%, FEV6, FEV1/FEV6, PEF, FEF25-75
Crapo 1981	FEV0.5, FEV3, FEV3/FVC
Morris 1971	FEF0.2-1.2
ECCS/Quanjer 1993	FEF25, FEF50, FEF75

The primary norm takes precedence over the composite source. For example, since the Crapo norm supports the FVC parameter, this value always comes from Crapo, not from the composite source.

Composite values are used when the patient does not fit the demographics of either primary norm (adult or pediatric). For example, if the primary norms are Dockery and Morris, a 14-year-old patient fits neither norm due to age restrictions. The software would use values from the appropriate composite norms, for example, NHANES III or ECCS/Quanjer 1993. It would not use values from Dockery or Morris.

On the screen and in reports, an abbreviation identifies the norm source for each composite value used. For example, the abbreviation for Polgar is "po." All norm abbreviations are listed under "Norm Profiles" on page 68.

Also see "Norm Profiles" on page 68 for a listing of the parameters included in each norm.

To learn how to enable or disable composite norm values, see "Reviewing the Operation Settings" on page 13.

About Lung Age

Lung age is a calculated value based on a patient's demographics and spirometric performance that gives a relative indication of the health of the subject's lungs. This value is used primarily to encourage smoking cessation.

The CP 200 spirometer, calculates lung age values according to the document cited in Reference 5 on page 76 (Morris 1995). For single-effort tests, lung age is based on the current effort. Otherwise, it is based on the patient's "best" effort, as defined in the settings.

Lung age results less than 20 years are reported as "<20," and results greater than 84 are reported as ">84." This limitation is derived from the subject population on which Morris based his research.

Lung age, which is expressed in years, is the average of the four formulas in the Morris article (FVC, FEV1, FEF25-75%, and FEF0.2-1.2). Specifically, lung age is calculated as follows:

Gender	Lung Age Formula
Men	[5.920 (height) – 40.000 (FVC) – 169.640 + 2.870 (height) – 31.250 (FEV1) – 39.375 + 2.319 (height) – 21.277 (FEF200-1200) + 42.766 + 1.044 (height) – 22.222 (FEF25%-75%) + 55.844] / 4
Women	[4.792 (height) – 41.667 (FVC) – 118.833 + 3.560 (height) – 40.000 (FEV1) – 77.280 + 4.028 (height) – 27.778 (FEF200-1200) – 70.333 + 2.000 (height) – 33.333 (FEF25%-75%)+18.367] / 4

About Quality Feedback

The spirometer provides two kinds of quality feedback: effort-quality messages and test-quality grades, as described in the following sections.

About Effort-Quality Messages

One of the following effort-quality messages appears on the screen after each effort is completed. These messages indicate whether an effort was acceptable and reproducible, and if not, what the patient needs to do differently.

For an example of the "effort complete" screen where these messages would appear, see Figure 30 on page 44.

The term "match" here means "variation" or "difference with respect to best test."

Effort-Quality Message	Criteria
Don't hesitate	Back-extrapolated volume > 150 mL or 5%, whichever is greater.
Blast out faster	PEF time > 120 ms.
Blow out longer	FET < 6.0 seconds, and end-of-test volume > 100 mL (invalid FEV6).
Blast out harder	PEF is not reproducible (match > 1.0 L/s).
Deeper breath	FEV6 match > 150 mL FVC may be substituted for FEV6.
Good effort	Effort meets above criteria.
Good test session	Two acceptable efforts match.

About Test-Quality Grades

Another type of feedback is the test-quality grade, as described in the following table. If **Print Quality Grades** is enabled in the settings, a grade appears on printed reports and also displays on screen when you view the values or interpretation of a completed test (as described under "To View a Test's Results" on page 46).

To learn how to enable or disable this setting, see "Reviewing the Spirometry Print Settings" on page 17.

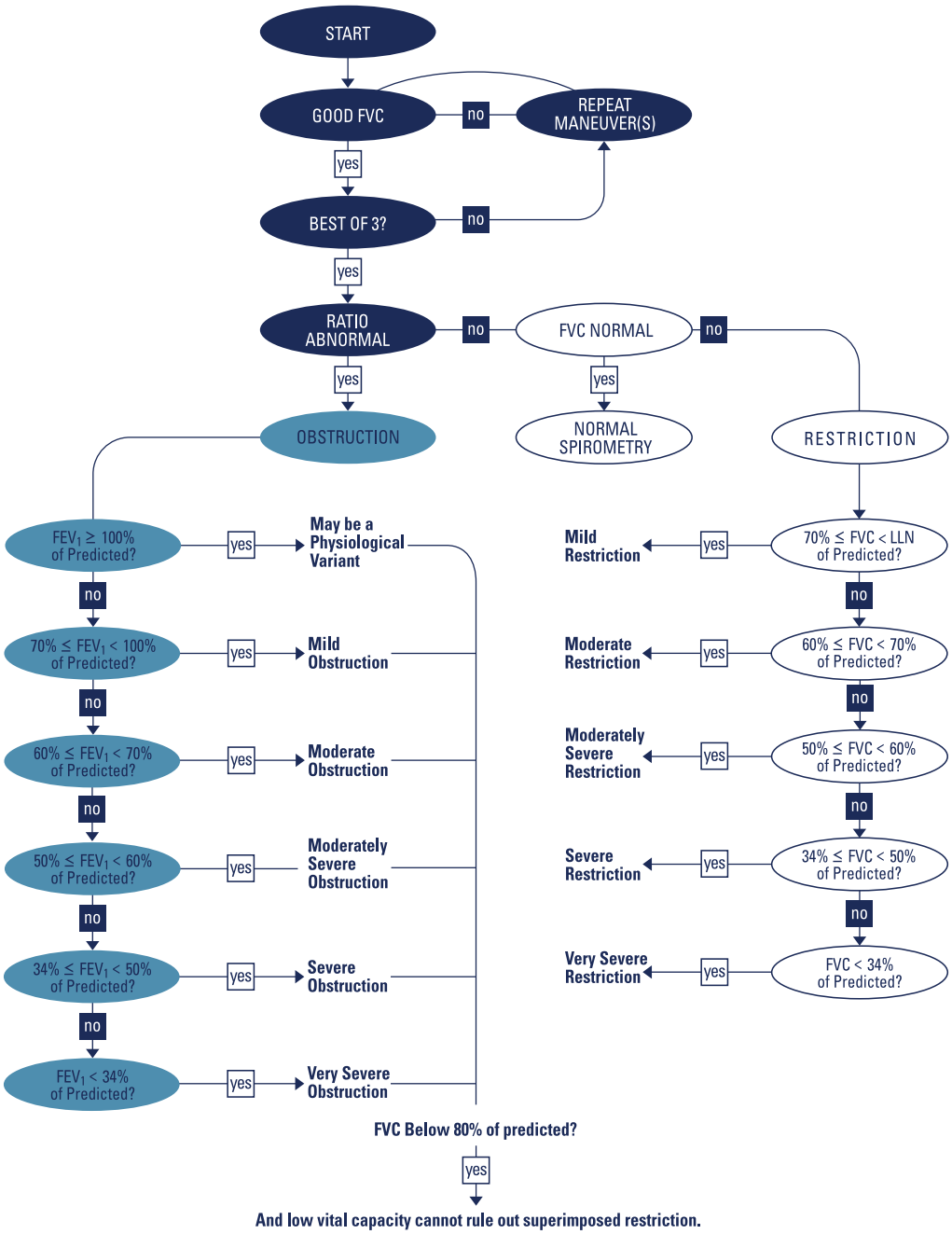
Test-Quality Grade	Number of Acceptable Efforts	Reproducibility
A	2 or more	Largest two FEV1 values match ≤ 100 mL. Largest two FVC values match ≤ 100 mL.
B	2 or more	Largest two FEV1 values match > 100 and ≤ 150 mL.
C	2 or more	Largest two FEV1 values match > 150 and ≤ 200 mL.
D	1 or more	Largest two FEV1 values match > 200 mL.
F	None	

Understanding Your Interpretation Results

This diagram shows how the automatic interpretation software uses a patient's FVC and FEV1 results, in comparison with normal values, to determine the degree of obstruction or restriction. This diagram follows the American Thoracic Society's example for interpretation.

For details on interpretative strategies, see the document noted in Reference 9 on page 76.

Figure 36. Data Interpretation, Process Diagram



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   See in particular the calibration and reporting sections of this document.

3. *Lung Function Testing: Selection of Reference Values and Interpretive Results,* American Thoracic Society, March 1991.

   This document describes the methods of selecting the reference values and the algorithm for interpretative results.

4. *National Occupational Respiratory Mortality System,* National Institute for Occupational Safety and Health (NIOSH).

5. *Short Report Spirometric "Lung Age" Estimation for Motivating Smoking Cessation,* James F. Morris, M.D., and William Temple, Preventive Medicine 14, 655-662 (1985).

6. *Standardization of Spirometry, 1994 Update,* American Thoracic Society.

   This document describes the methods of acquiring the output parameters and the required accuracy. For details on ATS acceptability criteria, see these sections:

   - "FVC — Satisfactory Start of Test Criteria," page 1120
   - "FVC — Test Result Reproducibility," page 1122

7. *Standardized Lung Function Testing,* European Respiratory Journal, volume 6, supplement 16, March 1993.

8. *U.S. Pulmonary Function Standards for Cotton Dust Standard,* 29 CFR 1910.1043, Appendix D.

9. *Lung Function Testing: Selection of reference values and interpretive strategies.* American Thoracic Society, American Review of Respiratory Disease, 144:1202-1218 (1991).

Glossary

adult. Generally, 18 or older. Age limits vary with each norm.

ATS. American Thoracic Society. An organization that provides standards for spirometry common practice and equipment.

ATS acceptability criteria. Applicable to FVC testing only. (1) Criteria ensuring that an individual effort started and ended satisfactorily (no leaks or coughs). (2) Criteria ensuring that the patient has made at least two efforts of the same kind (two FVC-pre or two FVC-post), and that these efforts are reproducible. For details, see document noted in Reference 6 on page 76.

ATS interpretive results. The software generates interpretive results as described in the document noted in Reference 3 on page 76.

baseline. See pre-test.

best effort. A measurement calculated from a set of efforts. The formula for calculating best effort is user-selectable: (1) the single best effort or (2) a composite of best parameter values.

BF. Breathing frequency. See also MV and tidal breathing.

bronchospasm evaluation. See post-test.

BTPS. Body conditions, normal body temperature (37° C), ambient pressure, saturated with water vapor. The BTPS correction factor converts ambient conditions — temperature, humidity, and pressure — to BTPS.

CardioPerfect workstation. A PC using Welch Allyn CardioPerfect software. Stores ECG and spirometry test data. Can communicate with other electronic patient-information systems, such as billing and medical records.

composite norm value. A value that is filled in from another norm — a "composite norm source" — when the primary (selected) norm does not support a given parameter. Applicable only when composite norm values are enabled.

COPD. Chronic obstructive pulmonary disease. Characterized by airflow obstruction that is primarily caused by smoking. Examples include emphysema, chronic bronchitis, and asthmatic bronchitis.

curve. A graphical display of spirometry data. During SVC testing, only one curve type is available: volume/time. During FVC testing, four curve types are available: volume/time, flow /volume, tidal volume, and (on screen only) incentive.

effort. A single spirometry maneuver, for example, one blow. A single test comprises multiple efforts. See also best effort.

ERS. European Respiratory Society.

ERV. Expiratory reserve volume (in liters). The maximum volume that can be expired from the level of the functional residual capacity (FRC). See also tidal breathing.

extrapolation. The practice of applying a norm's formula to a patient who doesn't fit that norm's demographics. For example, if you were testing an 88-year-old man, and the primary (selected) norm were based on males 85 or younger, the predicted values would be extrapolated values.

FEF50/FIF50. The ratio of these two parameters. See FEF50 and FIF50.

FEF25. Forced expiratory flow (in L/s) at 25% of FVC.

FEF50. Forced expiratory flow (in L/s) at 50% of FVC.

FEF75. Forced expiratory flow (in L/s) at 75% of FVC.

FEF85. Forced expiratory flow (in L/s) at 85% of FVC.

FEF0.2-1.2. Forced expiratory flow average (in L/s) between 0.2 and 1.2 liters of FVC.

FEF25-75. Forced expiratory flow average (in L/s) during the middle half of FVC.

FEF75-85 ("late" FEF). Forced expiratory flow average (in L/s) between 75% and 85% of FVC.

FET. Forced expiratory time (in seconds). The elapsed time from the beginning of expiration until a specified percentage of FVC.

FEV0.5. Forced expiratory volume (in liters) at 0.5 seconds.

FEV1. Forced expiratory volume (in liters) at 1 second. An important parameter because it reflects the severity of COPD.

FEV1/FEV6. The ratio of these two parameters. See FEV1 and FEV6.

FEV1/FVC. See FEV1%.

FEV2. Forced expiratory volume (in liters) at 2 seconds.

FEV3. Forced expiratory volume (in liters) at 3 seconds.

FEV5. Forced expiratory volume (in liters) at 5 seconds.

FEV6. Forced expiratory volume (in liters) at 6 seconds.

FEV0.5%. FEV0.5 as % of FVC.

FEV1%. FEV1 as % of FVC. Same as FEV1/FVC. A parameter for a single FVC effort.

FEV1% formula. A user-selectable formula that determines the calculation method for a test's (not an effort's) overall FEV1% value, which affects the automatic interpretation.

FEV2%. FEV2 as % of FVC.

FEV3%. FEV3 as % of FVC.

FEV5%. FEV5 as % of FVC.

FEV6%. FEV6 as % of FVC.

FEVt. Timed forced expiratory volume (in liters). Volume of air exhaled in the specified time during an FVC effort.

FIF50. Forced inspiratory flow (in L/s) at 50% of FIVC.

FIV1. Forced inspiratory volume (in liters) at one second.

FIV1%. FIV1 as % of FIVC.

FIVC. Forced inspiratory vital capacity (in liters). The maximum volume of air that can be inspired during forced inspiration starting from full expiration.

FIVt. Timed forced inspiratory volume (in liters). Volume of air inhaled in the specified time (t).

flow. The speed at which air is inhaled or exhaled (in L/s).

flow = f(v). See flow/volume.

flow/volume. Same as *flow over volume* or *flow = f(V)*. A type of data curve available during FVC testing. The y axis represents flow (L/s); the x axis represents volume (liters).

flow loop. A flow/volume curve that includes inspiratory data (negative values on the y axis).

FRC. Functional residual capacity (in liters). Volume of air remaining in the lungs and airway at the average end-expiratory level.

FVC. Forced vital capacity. (1) A type of test in which patients inhale fully and exhale forcefully for as long as they can. The goal: to measure the volume and flow of air. May or may not include forced inhaling. When forced inhaling is included, it may be done either before or after exhaling. See also flow loop. (2) An important parameter (in liters): the maximum volume of air that can be delivered during forced expiration starting from full inspiration.

IC. Inspiratory capacity (in liters). The maximum volume of air that can be inhaled after a normal — unforced — exhalation. See also tidal breathing.

incentive screen. An animated screen that gives patients — usually children — a goal to achieve while exhaling. This screen is listed as a type of "curve" (data display) available during FVC testing.

IRV. Inspiratory reserve volume (in liters). The maximum volume that can be inspired from the average end-inspiratory level. See also tidal breathing.

LLN. Lower limits of normal. The lowest expected value for a spirometric parameter. The method of determining this value varies from norm to norm.

loop. See flow loop.

lung age. A calculated value based on a patient's demographics and spirometric performance that gives a relative indication of the health of the subject's lungs. This value is used primarily to encourage smoking cessation. Lung age is not available for patients under 20 years of age.

maneuver. See effort.

MV. Minute volume (in liters). MV = BF · VT. See also tidal breathing.

NIOSH. National Institute for Occupational Safety and Health (U.S.).

norm. A research-based spirometry data set with a specific profile for race, gender, age, and height. The software compares each patient's results with data in the primary (selected) norm, reporting the results as percentages of the predicted (normal) values.

normal. Consistent with norm data.

OSHA. Occupational Safety & Health Administration (U.S.).

parameter. A commonly defined attribute of a spirometric waveform (FVC, FEV1, and so on).

pediatric. Generally, under 18 years old. Age limits vary with each norm. Also, young children's lung sizes vary greatly. Norm values and interpretive results are not available for patients under 3 years of age.

PEF. Peak expiratory flow (in L/s). The largest expiratory flow achieved with a forced effort.

PIF. Peak inspiratory flow (in L/s). The largest inspiratory flow achieved with a forced effort.

post-test. A test that provides data to compare with pre-test data. Sometimes called *post-Rx* or *post-BD* (bronchodilator). A post-test must follow a pre-test within 24 hours. See also reversibility.

predictive curve. A curve that follows a set of predictive points.

predictive points. Key values from the selected norm and from composite norms (if enabled). Applicable for FVC tests only. For flow/volume curves, predictive values are PEF, FEF25, FEF50, FEF75, and FVC (all represented as points). For volume/time curves, predictive values are FEV1 (represented as a point) and FVC (represented as a horizontal line). If predictive points are enabled, all available predictive values appear on the screen and the printout.

pre-test. A test that provides a baseline for comparison with a post-test taken by the same patient. Sometimes called *pre-Rx* or *pre-BD* (bronchodilator). Pre-tests and post-tests are commonly used to evaluate the effectiveness of medication. See also reversibility.

reversibility. The percentage difference between pre-test and post-test data. This measurement indicates the effect of medication on lung function. Reversibility applies to each parameter separately. The reversibility formula, which determines the way in which reversibility is calculated, is user-selectable.

SVC. Slow (relaxed) vital capacity. (1) A type of test in which patients breathe normally several times, then inhale maximally and exhale maximally, or vice versa. Sometimes SVC testing is used when forced breathing is impossible. The patient inhales and exhales as completely as possible, as in FVC testing, but the breathing is not forced. The goal of an SVC effort is to measure the volume of air inhaled and exhaled, not the air flow (speed). (2) An important parameter (in liters): the maximum volume of air exhaled from the point of maximum inhalation, or maximum volume of air inhaled from a point of maximum exhalation.

test. A set of efforts — up to 6 efforts of each type (FVC and SVC) for a maximum of 12 efforts (6 FVC and 6 SVC). The 6 efforts of a given type can be a mixture of pre-medication and post-medication efforts.

Tex. Tidal breathing expiration time (in seconds). See also tidal breathing.

tidal breathing. Multiple breaths, normal breathing. May be used during FVC or SVC testing. After measuring tidal breathing for several seconds, the following parameters can be extrapolated: MV, VE, BF, and Tin/Tex. If you combine a VT measurement with a VC measurement, you can also calculate the ERV, IC, and IRV. For example, COPD patients have a higher ERV and a lower IC and IRV.

tidal volume. See VT.

tidal volume curve. A flow loop that includes all data from all breaths, tidal and forced.

Tin. Tidal breathing inspiration time (in seconds). See also tidal breathing.

Tin/Tex. The ratio of Tin and Tex. See also Tin and Tex.

TV. See VT.

variance. The difference between the best and worst efforts for a parameter (FEV1, FVC, and so on). Pre-test and post-test variances are reported separately. See also best effort.

VC. Vital capacity. See FVC or SVC.

VE. Ventilation in L/min. See also tidal breathing.

vital capacity. See FVC or SVC.

volume = f(t). See volume/time.

volume/time. Same as *volume over time* or *volume = f(t)*. A type of data curve available during both FVC and SVC testing. The y axis represents liters; the x axis represents seconds.

VT. Tidal volume (in liters). Also called TV, although VT is the preferred abbreviation. The volume of air that enters the lungs during inspiration and leaves the lungs during expiration in a normal breathing cycle. One of the most important parameters in SVC testing. See also MV, tidal breathing, and tidal volume curve.

workstation. See CardioPerfect workstation.

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